دستور الأدوية الدولي

The International Pharmacopoeia

منتدى إقرأ الثقافي
للكتب (كوردى - عربي - فارسي)
www.iqra.ahlamontada.com

الطبعة الثالثة

Third Edition

Volume 2
Quality specifications

المجلد الثاني
مواصفات الجودة

تمت الترجمة في المركز العربي للتعريب والترجمة والتأليف والنشر بدمشق

منظمة الصحة العالمية 1981

World Health Organization 1981

Ĭ ǁǸǰơǁƐ ƕĭǸǰơŬƐ ƥǸǰƗ ƨơ

The International Pharmacopoeia

ƕǩǁƑǩǁƐ ƕƴƓŬǁƐ

Third Edition

Volume 2 — Ĭ ǆƑǩǁƐ ơǂƜƊǁƐ

Quality specifications — ǫơǸǰƜǁƐ ƖƑƧƬ ƐǸǰǅ

[illegible]

1981 [illegible]

World Health Organization 1981

[illegible]

[illegible]

[illegible]:

- [illegible]:

1. [illegible] 1 [illegible] 2 [illegible] 372.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1 AND 2

2. [illegible] 1 [illegible] 2 [illegible] 3 [illegible] 310.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2 AND 3

3. [illegible] 1 [illegible] 2 [illegible] 3 [illegible] 4 [illegible] 256.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2,3 AND 4

[illegible].

- [illegible].

- [illegible]:

R [illegible] RS [illegible] TS [illegible] VS [illegible].

[illegible].

[illegible]

[illegible]

[illegible]

[illegible]

[illegible] *International pharmacopoeia* [illegible] .WHA3-10[1] [illegible]

[illegible] .[2][illegible] 1 [illegible] [3][illegible]

[illegible] 1979-1977 [illegible] 2 [illegible] WHO Expert advisory Panel [illegible] 1980/[illegible] 2 [illegible]

[illegible] 2 [illegible] .[illegible]

.127 [illegible] 1979 [illegible] 1 [illegible] .[1]

.1979 [illegible] 1 [illegible] .[2]

.1980, 645 [illegible] .[3]

[illegible]

[illegible]

[illegible]

[illegible] 126 [illegible] 2 [illegible]

[illegible]

[illegible] 2 [illegible] 1 [illegible] 1 [illegible]

[illegible] Box 3045, 171 03 solna, 3, Sweden [illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

GENERAL NOTICES [illegible]

Monograph nomenclature [illegible]

[illegible] *International Nonproprietary Name (INN)*.

[illegible] (Ethosuximidum.

nominative [illegible] Codeini) [illegible] genitive [illegible] (phosphas. [illegible] Natrium [illegible] "Natricus" [illegible] Cloxacillinum [illegible] Cloxacillinum natricum.

[illegible] *International pharmacopoeia*. [illegible]

[illegible]

Chemical formulas [illegible]

[illegible]

Chemical names [illegible]

[illegible] .International Union of pure and Applied chemistry (IUPAC) [illegible] IUPAC [illegible] Chemical Abstract Service (CAS NO.) [illegible] .American Chemical Society

Identity tests [illegible]

[illegible] analyst [illegible] Spectrophotometer [illegible] "Identity tests [illegible]

Impurities [illegible]

[illegible] limits [illegible]

Water [illegible]

[illegible] .demineralized

Clarity of solution [illegible]

[illegible] "Colour of liquids [illegible] 1 [illegible]

[illegible] opalescence standard TS2 [illegible]

[illegible]

.TS2 [illegible]

Colourless solution [illegible]

[illegible] "Colour of liquids [illegible] 1 [illegible]

[illegible] RdO [illegible] GnO [illegible] YwO [illegible] BnO [illegible]

[illegible]

Indicators for visual determination of pH values [illegible]

[illegible] pH [illegible]

.[illegible] pH [illegible]

Water - bath [illegible]

[illegible] (°[illegible] 100 [illegible]) [illegible]

.[illegible]

Examination in ultraviolet light [illegible]

[illegible] 365 [illegible] 254) [illegible]

.[illegible] 365 [illegible] 254 [illegible]

Loss on drying [illegible]

.[illegible]

Containers [illegible]

.1 [illegible]

[illegible] .*Hermetically closed container* [illegible]

[illegible] handling [illegible]

Stability information [illegible]

[illegible]

Category [illegible]

[illegible] therapeutic [illegible]

MONOGRAPHS ƖɛƍǋɓøʓǓɛ

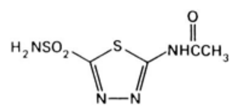
ACETAZOLAMIDUM

Acetazolamide ǫǐǲǗǌǬƑǐ ƨ ƈ

$C_4H_6N_4O_3S_2$ ¦**Molecular formula** ǦȅǺǺƨǟ Ǧ8ǯÔǟ

222.2 ¦**Relative molecular mass** ǦǯǤÊǞǟ ǦǯǺǺƨǟ ǦŸǪȮǟ

¦**Graphic formula** ǦǬǫǺǯǤȼǟ Ǧ8ǯÔǟ



¦**Chemical name** ȗǝǺǯȶǯȮǟ ǀèƭǟ

N-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)acetamide; *N*-[5-(amino-sulfonyl)-1,3,4-thiadiazol-2-yl]acetamide; 5-acetamido-1,3,4-thiadiazole-2-sulfonamide; CAS Reg. No. 59-66-5.

.ǦȗǝǟǞǟ ȻǼȝ ǕɃøƺŸǟ ǕǺǤǞǞǑǩ Ȑǯǟ ȿǟ ǕȐǯǟ ȧƺȗÊǋ :**Description** ƺòƺǟ

ǟǟȿǟ ƘǳǕTS (ȯ/ȟ 750 ~) ȯƺǬǺǯǟǭǟ Ž ȷǟǟȿØǟǟ ǴǯȗǊ ǕǟȶǕ Ž ǟǼǱ ȷǟǟȿØǟǟ ǴǯȗǊ :**Solubility** ǦǬǟǟȿØǟǟ

.ǟǯŸȶȝ R ȳøƺƺȿøƺŸȮǟ Ž ƭȿ R ƘǫȷǕ Ž

.ǦǯǫƺǟǞȮǟ ǟǟøǼǯǼȷǟ ȖǦǯǋ ¦**Category** ǦǟǟǞǟ

.ǟǼǱ ǦǕŸ8ǋ ǦǞȿǟǵ Ž ǼǯǋƭȿǟǺǬǯèȷǟ Ȿǟǵ Ǽȥ :**Storage** ȸǟÂǺǪǟ

REQUIREMENTS ƘǴȗǯƱƙǆ!ƒ

%101.5 ȸȝ ǼǺǺ ƭȿ % 9.0 ȸȝ ǑǑǟ ƭ ǟǋ ʔǕȝ ǼǯǋƭȿǟǺǬǯèȷǟ ɃƺǪȜ :**General requirement** ȳǺǟǟ ǼŸǕǪȶǟ

.ǦǟǞȮǟ ǥǟǟȶǟ Ƃǯ ȶƺǱǞǟǟǟ ǦǟƺÊȚ Ǖ$C_4H_6N_4O_3S_2$ ȸǋ

¦**Identity tests** ƕǐǌǈǁ ǀ ǫƥƑǴȡǁ

ǟǟǟȶƩǟ ƘƠ ǦȞǐȷǟ ǦǑǕǟǋ Ž ȗǝƺȒǟ ƺǯǕǟ ǟǟǯȩ" ȷǟƺǟȝ ƘƠ 8ƺòƺǋ ƺȴ ǟȶǒ ÒȗǟǞǟ ǯǤǕǺ :A

ƘƠ ǦȞǐȷǟ Ž ǐ ǟÔǪǋƭǟ ƺǯù ǯǟǟǕǪǺ .(43 ǦȗǟÔǟǟ Ǖ1 ǼŸǑǟ) "Spectrophotometry in the infrared region

.ǼǯǋƭȿǟǺǬǯèǪǟ *reference spectrum* ȗȞǱǟȶǟ ƺǯǕǟǟ ȝǋ ȿǟ RS ǼǯǋƭȿǟǺǬǯèȷǟ ȸǋ ȷǩǟǟǟ ƺǯǕǟǟ ȝǋ ǟǟǟȶƩǟ

0.1% VS (v/v 1) [illegible] 0.15 [illegible] 5 [illegible] 25 [illegible] :B

.[illegible] TS (v/[illegible] 80) (II) [illegible]

[illegible] 0.2 [illegible] VS (v/v 1) [illegible] 1% [illegible] 5 [illegible] 0.5 [illegible] :C

[illegible] TS (v/[illegible] 420 ~) [illegible] 0.5% R [illegible]

80) [illegible]

.[illegible] TS (v/[illegible]

[illegible] 1.0 [illegible] :**Heavy metals** [illegible]

[illegible] (127 [illegible] 1 [illegible]) 3 [illegible] "Limit test for heavy metals [illegible]"

.[illegible] 20 [illegible] (128 [illegible] 1 [illegible]) A [illegible]

[illegible] 5 [illegible] °C 70 [illegible] 40 [illegible] 1.0 [illegible] :**Sulfates** [illegible]

[illegible] 1 [illegible]) "Limit test for sulfates [illegible]"

.[illegible] 0.5 [illegible] (116 [illegible]

.[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

[illegible] °C 105 [illegible] :**Loss on drying** [illegible]

.[illegible] 5.0

.6.0 - 4.0 [illegible] 5 [illegible] 50 [illegible] 1 [illegible] :**pH value** [illegible]

[illegible]" [illegible] :**Related substances** [illegible]

[illegible] R2 [illegible] (84 [illegible] 1 [illegible]) "Thin - layer chromatography [illegible]

[illegible] 20% R [illegible] - 2 [illegible] 30% [illegible] 30 [illegible] coating substance

[illegible] Xylene R [illegible] 10% R [illegible] 10% TS (v/[illegible] 35 ~) [illegible]

[illegible] 5.0 [illegible] :(A) [illegible] TS (v/[illegible] 750 ~) [illegible] 20 [illegible]

[illegible] 1 [illegible] 0.050 [illegible] :(B) [illegible] 1 [illegible]

.([illegible] 254) [illegible]

.B [illegible] A [illegible]

[illegible] R [illegible] 90 [illegible] 0.45 [illegible] :**Assay** [illegible]

[illegible] VS (v/v 0.1) [illegible]

[illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) B [illegible] "Non-aqueous titration [illegible]"
.$C_4H_6N_4O_3S_2$ [illegible] 22.22 [illegible] VS ([illegible] 0.1) [illegible]

ØØØØØ

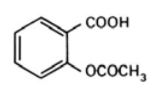
ACIDUM ACETYLSALICYLICUM

Acetylsalicylic acid [illegible]

$C_9H_8O_4$:**Molecular formula** [illegible]

180.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2-(Acetyloxy)benzoic acid; 2-acetoxybenzoic acid; CAS Reg. No. 50-78-2.

.[illegible] :**Description** [illegible]

[illegible] TS ([illegible] 750 ~) [illegible] 300 [illegible] :**Solubility** [illegible]
.R [illegible] R [illegible]

.[illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]
.[illegible]

REQUIREMENTS [illegible]

[illegible] %99.0 [illegible] :**General requirement** [illegible]
.[illegible] $C_9H_8O_4$ [illegible] %100.5 [illegible]

Identity tests [illegible]

([illegible] 25) [illegible] 2 - 1 [illegible] 2 [illegible] 0.05 [illegible] :A

.TS (ȯ/ȟ 750 ~) ȯȥȹǯɋ ǦȥȂȓ ȯǼ ɍ ȖȦƥ – ȴǲȆȦ ɂȥ ǯȹ ȖTS

ȭ 5 ȣȦȒȘ ȖǻȞ ȖĘȦȩǻ 3 ǦȦȘ TS (ȯ/ȟ 80 ~) ȳȥǻȥȎ ǼȆȭȘǾ ȯȥȚ ȡ ȭ 4 ȝ ȟ 0.2 ȝȣ :B

Ȗ(C ǾȦȵȒ ǦǵȦȈ ȘȞ) Ǵȋ .ȯȦȒ ǦǾȥ ǦȦȅǾ ǯȹ ȖTS (ȯ/ȟ 100 ~) ȭǾȥȦȆ Ȑƥ ȯȥȚ ȡ

.(ȭȆȦȆ Ȑƥ) °ȳ 159 ǦȦȘ ǾȦȎȍ ǥǾȦǵ ǦǲǾǻ .°ȳ 105 ǥǾȦǵ ǦǲǾǼ ȤȦȺȘ ȯȦȶ ǦȦȅȦ ȬȆȣ

ȯȥȚ ȡ ȭ 2Ș TS (ȯ/ȟ 750 ~) ȯȥȹǯɋ ȯȥȚ ȡ ȭ 2 ȝ B ǾȦȵȍ ȡ ǦȺȦ ǦǵȦȈ ȡǺȆȣ :C

ȝ ȬȞ ȻȦȥ) ȦȠǾ ȡ ȦȠȭǾǻ ȡȮȥ ȴǾȦ ȖȮǯɋ ǧȦȅ ǯȹ ȖTS (ȯ/ȟ 1760 ~) ȭǾȥȦȆ Ȑƥ

.(ǾǾȝ)

ǾȦȵȒȍ ȯȥȚ ǨȒȘ R ɂȥȅȷ ȡ ȭ 25Ș ȟ 1.0 ȬȞȆ :**Heavy metals** ǦȭǯȦ (ǧȦȂȦ) ɂǻȞȶ

ȦȂǲɋ Ȗ"Limit test for heavy metals ǦȭǯȦ ɂǻȞȬ ȭǲȷ ȻǼȝ ǾȦȵȒȍ" ɂȥȝ ȞƠ ȣȥȒȥ ȥȽ Ȧȡ ǼȆɯ

20 ȡȝ ǼȂȂ ɍ Ȗ(128 ǦȞȎȦ Ȗ1 ǼȚȭ) A ǦȭȂȖȭ Ȭȥ ȬȭǯȦ ɂǼȞȶ ȝȥȚ ȡȞ Ȗ(127 ǦȞȎȦ Ȗ1 ǼȚȭ) 2

.ȟ/ȳȦȡȘȭ

(ȯ/ȟ 750 ~) ȯȥȹǯɋ ȡ ȭ 10 Ž ȟ 1.0 ȂȭȦ ȯȥȚ ɂȥȮ :**Solution in ethanol** ȯȥȹǯɋ Ž ɂȦȘǾ

.ɂȥȚ ǼȝȘ ȬȥȦȒ TS

ȳȥǻȥȎ ǧȦȥȦȭ ȯȥȚ ȡ ȭ 10 Ž ȟ 0.5 ȂȭȦ ȯȥȚ ɂȥȮ :**Solution in alkali** ȺȥȚ Ž ɂȦȘǾ

.ȬȥȦȒ TS (ȯ/ȟ 50) ǦȦȥǼ

.ȟ/ȠȚ 1.0 ȡ ȦǯȭȖ ȆȞ :**Sulfated ash** ǨȦȚȆȶ ǻȦȠȦ

ȐȦǺȠ ȖȣȒ ǨƠ ȖȞ ǥǾȦǵ ǦǲǾǻ Ǽȝ ǨȦǯ ɂȦȥ ȝȮǵ ȤȦǲȽ :**Loss on drying** ȤȞǲȭȦ ǼȬȦ

5.0 ȡ ȦǯȭȖ ǼȭȂ ɍ ȖR ȖȦȮȆ ǦȠȴ ȤȦƒ ȧȥȥ (ĘȦ ȦȠ ȴȞ 5 ǦȦȘ ȘȖ ȯȦȮȅȦ ȥȚȭ 0.6 ȡȝ ǼȂȂ ɍ)

.ȟ/ȠȚ

TS (ȯ/ȟ 750 ~) ȯȥȹǯɋ ȯȥȚ ȡ ǦȥȦȭ ǦȶȭŽ ȟ 0.50 ȁȦǾ :**Salicylic acid** ȭȆȆȦȆ Ȑƥ

Ž R ȭȆȆȦȆ Ȑƥ ȡ ȟ 0.040 ȲȎȦȠ ȁȦǾ .ǦǾȦȭ ȁȥȖ ȻȖ ȭ 10 ȭȦȘ ȭ 25 ǾǼȭ ȴǲǵ ȯȦȖȝɋ

10 ȼȭȖ ȣȦȒȘ ȷȦ ǦǾȦȭ ȁȥȖ ȻȖ ȯȥȚ ȦǼ ȡ ȭ 1 ȭȦ .ȭ 100 ǾǼȭ ȴǲǵ ȯȦȖȝɋ ȯȦȶ ȡ ǦȥȦȭ ǦȶȭŽ

1 ǾȦ ǦȝȥȠ ȖȭȠ 50 ȝȝ ȯȥȎȝ ȝȮǵ ǨȥǦȷ ȲȭȻȖ ȯȦȶ ȣȦȒ .TS (ȯ/ȟ750 ~) ȯȥȹǯɋ ȯȥȚ ȡ ȭ

ɍ .ǦȭȘǻ 1 ǾȦȭȅȲ ȭȦȘ ǯȦȶȞ Ȗferric ammonium sulfate TS1 ȭǼǼȝ ȳȥȥȠȖ ǧȦȚȅ ȯȥȚ ȡ ȭ

ǨƠ ȣȥȒȥ ȥȽ Ȧȡ ǼȆɯ ɂǾȦȭ ȦȠǼȝ ȴǲȦȶ ȯȥȚ ɂȥ ȡ ǥǼȈ ȦǯȭȖ ǾȦȵȒȍ ȯȥȚ ȴǲȆȦȦ ɂȥȚ ɂȥȮ

2.0 ȡȝ ȭȆȆȦȆ Ȑƥ ȝȥȚ ǼȂȂ ɍ Ȗ(53 ǦȞȎȦ Ȗ1 ǼȚȭ) "Colour of liquids ȭȦȥȆ ɂȥ" ɂȥȝ

.ȟ/ȠȚ

БǓ VS (ȯ/ȯζɳ 0.1) ğǺǿζǣÀȮǟ ȡɳ БǺɿǟ ÿζʎåζÔǟ ǼĽÊõşøǼĿ ȯζŸȚ ȡɳ Ōɳ 50 8ǺȒʎ .**Assay** ǦÊʎǺŐʈǟ reflux ȗȝζǱǍÀǟ ȷǺʎÀƨǺǣ ŌȶȞʎ Ȥǧǿɳ ƘƠ ɁŸ8ɫş ÛǦĽüζǤȒɳ ȷşäζʈǟ ÛŌĽŸĽÊĽǿǺÊǟ ŌĽǬĽèǓ Ȑ þ ȟ 0.20 ǦǣǟǺę /ƙǺǿǺǬζ ȯζǼĽǺǟ ȯζŸȚ ȯǺȶȞǬèǺǣ ÛTS (ȯ/ȯζɳ 0.05) ŌʎøζǺŸÊǟ ȒȐ þ ȯζŸȞɳ ɃζŸÕǟ ğǻʎä ÀǺǺȞȽ .ĘəǺęǻ 10 ğǼɳ ȯζŸȚ ȡɳ Ōɳ 1 Ōõ .ǦʎøşÀȑ ğǺȞĽȞÔǨ ǦʎǓ ǾǺǬkş ǦòζȞǺʈǟ ğǻǺʈǟ ȷşǻ ǦĽŸȶȞǟ ǻǺȞǨ .ÀȞÎȶõ TS ȯζǿǺǯʎɋǟ .$C_9H_8O_4$ ȡɳ ȠŸɳ 9.008 ùζǺȮʎ VS (ȯ/ȯζɳ 0.1) ğǺǿζǣÀȮǟ ȡɳ БǺɿǟ ÿζʎåζÔǟ ǼĽÊõşøǼĿ

øøøøø

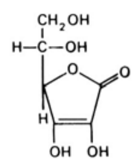
ACIDUM ASCORBICUM

Ascorbic acid þǏǤþǋǀƨǗƐ ƚ ƒ ǄǾ

$C_6H_8O_6$ ¦**Molecular formula** ǦĽǺʎÂƨǟ Ǧ8ĽÔǟ

176.1 ¦**Relative molecular mass** ǦĽǤÊǺǟ ǦĽǺʎÂƨǟ ǦŸǬȮǟ

¦**Graphic formula** ǦĽǿǺĽǤʈǟ Ǧ8ĽÔǟ



¦**chemical name** ȗəǺĽȶĽȮǟ ȴèɍǟ

CAS Reg. No. 50-81-7. ÜL-Ascorbic acid ÀÊĽʈǟ ŌĽǣøζȮèɉǟ Ȑþ

ǼǺȝ şǓ ǦȞəǟÀǟ ǼǺȝ ÜǦǤʎÀŌǨ ȐĽǣǓ şǓ ȐĽǣǓ ÛɃøζŸǣ ȧζȞÊɳ şǓ ȷζŸǟ ǦƹǼȝ ğǟøζŸǣ :**Description** Ȥòζǟ .ǦǤʎÀŌǨ ǦȞəǟÀǟ

R ƙǬɉǟ Ž ǼĽŸȶȝ ǟǟşǣ ƘȡÜTS (ȯ/ȟ 750 ~) ȯζǿǺǯʎɋǟ Ž ǟǟşǣ ÜõǺʈǟ Ž ȷǺǣşØǟ ǺǤ :**Solubility** ǦĽǿǺǣşØǟ .R ÿøζζşøζŸȮǟ Ž ɍş

.Antiscorbutic ȝǥǟ ǻǺȒɳ :**Category** ǦǺǺǟ

.òζȒǟ ȡɳ ǦĽȶȚ ÛǦĽǿǼĽȞɳ ɍ ÛÿǺȮǤüǣ ǦŌŸ8ɳ ǦʎşǺǤ Ž ŌĽǣøζȮèɉǟ Ȑþ ȘǺǤ Ǽƶ :**Storage** ȡʎÂǺǬǟ

ÜõǟζȚǟ ȝɳ ȼèǺȶǬǣ ǦȝÀÊǣ ȯζŸɉǟ Ž ŌĽǣøζȮèɉǟ ȒȐþ øζȽǼǬʎ :**Additional information** ǦĽζǺȑǓ ğǺɳζŸȞɳ ÛõζȒǟ ǟǺĽȡ Ž Ɂøǿǥ ÛǼùÀǟ ɃζƨǟÁ8Ÿ8Ÿõ ôÀȞǬǺǣ ǼĽƶøǼǨ ŌĽǣøζȮèɉǟ Ȑþ ŏǿǼǬş .ȒȒɳǺǤ ǺęǟØɳ ŌŸƩ .ɁŸȝɉǟ ğøǟÀƩǟ ğǺǱøǻ ǼʎȝȚ ţÀèǓ ŌȮǺǬǟ ȷζȮʎş

[illegible] %99.0 [illegible] **General requirement**: [illegible] %100.5 [illegible] $C_6H_8O_6$.

Identity tests [illegible]

A: [illegible] 0.1 [illegible] 2 [illegible] TS (~130 [illegible]) [illegible] TS (40 [illegible]) [illegible].

B: [illegible] 0.04 [illegible] 0.1 [illegible] R [illegible] 20 [illegible] 5 [illegible] TS (~100 [illegible]).

C: [illegible] 190 [illegible].

Specific optical rotation. [illegible] 50 [illegible] $[a]_D^{20\,°C} = +20.5$ to 21.5°.

Heavy metals: [illegible] 1.0 [illegible] "Limit test for heavy melals" [illegible] A [illegible] 1 [illegible] 128) [illegible] 20 [illegible].

Clarity and colour of solution: [illegible] 0.50 [illegible] 10 [illegible] Rd1 [illegible] "Colour of liquids" [illegible] 1 [illegible] 53).

Readily carbonizable substances: [illegible] 0.10 [illegible] 10 [illegible] TS (~1760 [illegible]) [illegible] 15 [illegible] Yw1 [illegible] Gn1 [illegible] "Colour of liquids" [illegible] 1 [illegible] 53).

Sulfated ash: [illegible] 1.0 [illegible].

Assay: [illegible] 0.20 [illegible] 25 [illegible] R 25 [illegible] (~100 [illegible]) [illegible] VS (0.5 [illegible]) [illegible] TS [illegible] 1 [illegible] VS (0.5 [illegible]) [illegible] 8.806 [illegible] $C_6H_8O_6$.

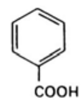
ACIDUM BENZOLCUM

Benzoic acid [illegible]

$C_7H_6O_2$:**Molecular formula** [illegible]

122.1 :**Relative mulecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Benzenecarboxylic acid; CAS Reg. No. 65-85-0.

[illegible] :**Description** [illegible]

[illegible] R [illegible] TS [illegible] (750 ~) [illegible] :**Solubility** [illegible] R [illegible].

[illegible] :**Ctegory** [illegible].

[illegible] :**Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] %0.99 [illegible] :**General requirement** [illegible] $C_7H_6O_2$ [illegible] %100.5 [illegible].

:**Identity test** [illegible]

[illegible] 5 [illegible] R1 [illegible] 0.1 [illegible] 0.1 [illegible] TS [illegible] 25) [illegible].

[illegible] 124 - 121 :**Helting rage** [illegible].

[illegible] 25 [illegible] 1.0 [illegible] :Heavy metals [illegible] R [illegible] 40 [illegible] 2 [illegible] R [illegible]

A ǦŐĂǕŶ ȂŐȥ Ǖ"Limit test for heavy metals ǦŶĚŐǰ ǰȷáĦţ ŐDZǰ ɃǼΣ øĂǫǹɍ" ȷȥȜ ǨƠ ȢȥǒȥȠ .ȟ/ÿĂɖşĂŎȠ 20 ȸȝ ǼĂ ɍ Ǖ(128 ǦĦĂÔ Ǖ1 ǼŶŎ)

ȸȠ ŌȠ 5 Ž ȟ0.35 ā ǾĂ ¦**Chlorinated compounds and chlorides** ğǼøȥŶŎş gǿȥŶǪţ ğĂǤõĂţ ʔŶȝ ȘǩȜ ǕŶĥõ ǈĦĂǩ ʔøǪǵ ǦĂȶǰ ȸǺÊǩş ǕȢĂƨ ʔøǪǵ ĂǺǤ ǕTS (ȯ/ȟ 50) ÿȥǻȥÔ ğĂȥǻõ ȯȥŶʈ (ȯ/ȟ 130 ~) ŌĂǪǼ Ȑ ƥ ȸȠ ŌȠ 12ş ŏţ ȸȠ ŌȠ 10 ȸȠ ǰĂȠ ǦĂȶǰ ǑǺǪÊǩ .°ÿ 400 ǨƠ gøĂΣ ǦDZøǻ Limit test for ğǼøȥŶŎ ŌDZǰ ɃǼΣ øĂǫǹɍ" ȷȥȜ ǨƠ ȢȥǒȥȠ ȥȽ ĂȠ ǼÊШ Ǧǵĭ Ăõ ŌȠĂĦ .Ǵĭ Ăş ǕTS .ȟ/ȠŶȠ 0.7 ȸȝ ğǼøȥŶŎ ʔȥǪʈ ǼĂ ɍ Ǖ(124 ǦĦĂÔ Ǖ1 ǼŶŎ) "chlorides

.ȟ/ȠŶȠ 1.0 ȸȝ ǼĂ ɍ ¦**Sulfated ash** ǨĂŶÊţ ǻĂȠĂ

Determination of water by ĂÎȄ ȯøĂõ ǦŐĂǕ ŏţ ǨĚĦ" ȷȥȜ ǨƠ ȢȥǒȥȠ ȥȽ Ăȶõ ȸĚĦ ¦**Water** ŏţ ȸȠ ĂȶDzǵ 2ş R ȯȥǰţ ȸȠ ĂȶDzǵ 1 ÿǼǺǪèĂ Ǖ(145 ǦĦĂÔ Ǖ1 ǼŶŎ) A ǦŐĂǕ Ǖ"the Karl Fischer method .ȟ/ȠŶȠ 7.0 ȸȝ ŏţ ʔȥǪʈ ǼĂ ɍ ǕǢǾȶõ R ȸǼǨ

1760 ~) ŌøȥŶÊ Ȑ ƥ ȸȠ ŌȠ 1.5 ȢȒȽ ¦**Readily oxidizable substances** ĦĂè gǼÊõǪ ǦŶĂŐ ǻȥţ ÿȥȄèĂȥ ğĂȢĂȠǨ ȯȥŶʈ ȸȠ ǕgĂǕŐȥ gĂǕę ǕȢȒĂş ǕȷǼŶȢ ʔøǪǵ ȸǺÊ ǕŏţȸȠ ŌȠ 100 Ƃ TS (ȯ/ȟ ĂŢÔĦȥ ǻĂţ gǻţ ȸȠ ȟ 1.0 ā ǾĂ .ǦĂǫ 30 (ɃǻøȥĂƥɟ) ɄŶĂŐ ȷȥŶ ȻǼǪÊ ʔøǪǵ VS (ȯ/ȯȥȠ 0.02) Ăƥɟ) ɄŶĂŐ ȷȥŶ ȻǼǪÊ ʔøǪǵ VS (ȯ/ȯȥȠ 0.02) ÿȥȄèĂȥ ğĂȢĂȠǨ ȯȥŶĦȠ ĂĂĦş ȸȒè ȯȥŶʈ Ž .VS (ȯ/ȯȥȠ 0.02) ÿȥȄèĂȥ ğĂȢĂȠǨ ȯȥŶʈ ȸȠ ŌȠ 0.5 ȸȠ ĂǰõǕ ǢǕǵ ɍ ǕǦǫ 15 gǼȠ (Ƀǻøȥ

ȯĚĦÊȠ ǕTS (ȯ/ȟ 750 ~) ȯȥǰǪ ȸȠ ŌȠ 15 Ž ǕǦùȥȒȠ Ǧşàȥ Ǖȟ 0.25 Ǧę ā ǾĂ ¦**Assay** ǦÊĂŐţ 0.1) ÿȥǻȥÔ ǼÊõşøǼȽ ȯȥŶĦȠ ĂĂĦş ǕŏţȸȠ ŌȠ 20 ȢȒȽ ǕTS ȯȥǰǪ/ȯȥǼĂ gĂȶǵ ȻDzǨ Ŷę ǦǕ ǾǺǩş ĂŢÔĦȥ ǻĂţ gǻţ ȷşǻ ǦŶȶĦ ǻĦǩ .ĂĦÎȶõ TS ȯȥǰǪ/ȯȥǼĂ gĂȶǵ ȯĂȶĦèĂ ǕVS(ȯ/ȯȥȠ ȸȠ ȠŶȠ 12.21) ùȥŎȽ VS (ȯ/ȯȥȠ 0.1) ÿȥǻȥÔ ǼÊõşøǼȽ ȯȥŶʈ ȸȠ ŌȠ 1 Őõ .ǦøşĂȓ ğĂĦĦÔǩ .$C_7H_6O_2$

øøøøø

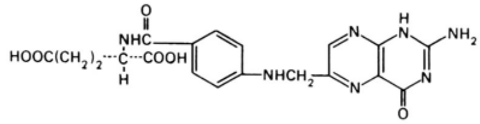
FOLICUM ACIDUM

Folic acid ƥĭǊƷƐ ɫƒ ǅϴ

$C_{19}H_{19}N_7O_6$ ¦**Molecular formula** ǦĂƨ Ǧ8Ô

441.4 ¦**Relative molecular mass** ǦÊĂ ǦĂƨ ǦŶǪŎ

:**Graphic formula** ǦǼǻÀǼǦƈǣ Ǧ8ǼÔöä



:**Chemical name** ǶǝÀǼȶǼÒöä ǈèǝä

N-[*p*-[[(2-Amino-4-hydroxy-6-pteridinyl)methyl]amino]-benzoyl]-L-glutamic acid; *N*-[4-[[(2-amino-1,4-dihydro-4-oxo-6-pteridinyl)-methyl]amino]benzoyl]-L-glutamic acid; CAS Reg. No. 59-30-3.

.ǦǶǝäÀöä ǅǼǆ ǼǦÀÕǨ ş ǦǶǝäÀöä ǅǼǆ ÜÀÀǒǪ ǟǿÀȑ ƂÀÕǨÀǣ ş ÀÀǒ ÛɃǿǭǼǣ ǻǭǶÊƞ :**Description** ǭǒǭöä

ǰǭǬèǰäş TS (ǿ/ȟ 750 ~) ǿǭǼǆǪäǅ ǟäşǣ Ƙǩ ǼǼȶǆ ÜǒÀǣ ǅ ǼǼǅǅ ǰÀǣşǾöä ǴǼǶǐ :**Solubility** ǦǼǻÀǣşǾöä

.R Ƙǫǰäş R ȳǿǭǭşǿǭÒöäş R

.Haemopietic ȳǼöä ǰǭǬƞ :**Category** ǦÀÀöä

.ǒǭȒöä ȡƞ ǦǼȶȚ ÛǼǼǅǅ ǦÕǿ8ƞ ǦÀşǵ ǅ ȬǼǭÀöä Ȑ Ƿ ǼǵƷ Ǽƶ :**Storage** ȡÀÂǺǪöä

REQUIREMENTS ƘǦǶǼƱƘdž!ƒ

ȡǆ ǼÀÂÀ ȑş %96.0 ȡǆ ȬÕÀ ȑ Àƞ ǝÝǆ ȬǼǭÀöä Ȑ Ƿ ɃǭǪǆ :**General requirement** ȳÀȞöä ǼǼÛǪȶä .ǦǼǝÀƞǶöä ǵÀȶä ƂÜ ȶǭǅǅÀöÀǣ ǼǼǭÊȚ Û$C_{19}H_{19}N_7O_6$ ȡƞ %102.0

:**Identity tests** ƕǏǊƝ ǀƐƑǴǪƐ

Ƙǣ Àƞ ÛVS (ǿ/ǿǭƞ 0.1) ȳǭÀǻǭÔöä ǼǼÊȭşǿǼȽ ǿǭÝȚ ǅ Ȭƞ/ȳäÀǯşÀÒƞ 15 ǿǭÝǂ ǐ ÀÔǪƞȑä ǭǼù ɃǼǼÀ :A

ǰǭÒǨş ÛÀǪƞǭǻÀǻ 365ş 283ş 256 ǦǼäÀǫ ǯäǭƞǰä ǿäǭùÜ ǅ ǦǼȶȚǆÜ ǧÀǒÀÔǪƞä 3 ÛÀǪƞǭǻÀǻ 350ş ÀǪƞǭǻÀǻ 230 ǈè 2 ÈǼǼǨ ǧäǨǅǵ ȳäǼÀǪèä ȬȒÀÀ) ƂäǭǪöä ǝÝǆ Û0.28ş 0.80 Û0.82 ǦǼäÀǫ ǯäǭƞǰä ȻǾȽ ǿäǭùÜ ǼÀǆ ǧÀǒÀȶǪöä ƂÜ ÀǪƞǭǻÀǻ 256 ǼÀǆ ǈè 1 ǦǻÀǺǯǣ ǦȬǦÛǿ ǐ ÀȶǪöä ǦǦÊǻ ǰǭÒǨş .(ǈè 1 ǦǻÀǺǯǣ ǦȬǦÛǿ ǐ ÀȶǪöä ǼÊǆş ǧÀèÀǼÕǭǿ .3.00ş 2.80 Ƙǣ ÀǪƞǭǻÀǻ 365 ǼÀǆ ǐ ÀȶǪöä

"Thin - layer chromatography ǦȬǼǫÀöä ǦȬǦÛöä ǟäÀǏǪèä" ǰäǭÀǆ ƘƠ 8ǭǒǭƞ ǭȽ Àƞ ǼÊǁ ǿÀǦǪǹȑä ǲǼÛǂ :B

-1 ȡƞ ǼȶǅǵǴ 2 ȡƞ ǰÀÂƞş coating substance ǦǾ8ƞ ǵÀȶȭ R1 ÀÒǼǼÊöä ǦƞȲȽ ǿÀȶǰǪèÀǣ Û(84 ǦǶÀÔöä Û1 ǼǼǑöä)

.ȭÀǶǪƞ ǿǭÛȭ TS (ǿ/ȟ 260 ~) ÀǼǭƞǰä ȡƞ ǼȶǅǵǴ 2ş ÛTS (ǿ/ȟ 750 ~) ǿǭǻÀǆǪäǅ ȡƞ ǼȶǅǵǴ 1ş ÛR ǿǭǻÀǣşÀǣ

ÀǼǭƞǰä ȡƞ ǼȶǅǵǴ 1ş R ǿǭǻÀǆǼǣ ȡƞ ȳǭǅǵǴ 9 ȡƞ ǰÀÂƞ ǅ ƘÀǪöä Ƙǿǭ ǝÝǆ ÀǪşÀÒƞ 2 ǦǶǼÀÔöä ǝÝǆ ǼÔÀÀƞ ǲǼÛÀ

ȡƞ ƞÝƞ 0.50 :Ƀǭǆ (B) ǿǭÝǂş Ȭƞ 1 Ȭȭ ǅ ǿÀǦǪǹȑä ǵÀƞ ȡƞ ƞÝƞ 0.50 :Ƀǭǆ (A) ǿǭÝǂä ÛTS (ǿ/ȟ 260 ~)

1 RS

A (365)

.B

2.0 **Sulfated ash**

Determination of water **Water**

0.15 (145 1) A by the karl Fischer method

90 70

AB T2 AT **Free amines**

.6 B1

50 0.050 T **Assay**

100 TS (~ 80) TS (~ 80)

(T_1 100 30.0

20 (B_1 100 30.0

B_1 T_1 TS (~ 70)

T_1 60 R 0.5 B_1

10 20

(T_2 100 10

(B_2 B_1 T_2 5.0

~70) 1 1 25

2 TS (1)

TS (5) ammonium sulfamat TS 1

TS (1) *N*-(1-naphthyl)ethylenediamine hydrochloride 1 2

10

B_2 B_1 T_2

A_B A_T 550

A_{BS} A_s RS

ǹǺƿǶǪǰǼ ǛǾǺǪǹƳ ǴǺǵ Ǯ ǦǭǺǵǳǾ ǴǺǷ ǻǵ ǦǴǷ ǦǦÊǺǾ ǧǺǵǛÔǵ $C_{19}H_{19}N_7O_6$ ǻǵ ʔǴǂǂ ÆÊǵƚ
ǻǵ (%) (¢ǹ ǳǺÔǷ) ǻǵǷ ʔǴǵǷǺ ǦǳǾǺǾ Ʒ ǳǺȒǩ ȳǹǾ Æǹǳ Û100 (10 A_T - A_B)/(10 A_S - A_{BS}) :Ǧ8ÔǾ
.ǦǶǳǺǷ ǦǭǺƿÔǾ ǴǺǷ Ǯ $C_{19}H_{19}N_7O_6$

ØØØØØ

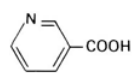
ACIDUM NICOTINICUM

Nicotinic acid ƿǐǻǐǏǐ ƒ ƊƟ

$C_6H_5NO_2$ ¦**Molecular formula** ǦǺǺȤ Ǧ8ÔǾ

123.1 ¦**Relative molecular mass** ǦǦÊǺǾ ǦǺǺȤ ǦǾÔǾ

¦**Graphic formula** ǦǺǦǷ Ǧ8ÔǾ



¦**Chemical name** ȔǺǭÔǾ ȴèƒ

3-Pyridinecarboxylic acid; CAS Reg. No. 59-67-6.

.ǺǺǺ ǦǶǺǺ ȻǺ ȿ ǦǶǺǺ ȻǺ ÜȒǺ ÛȜǺ ȧǵÊǷ ȿ ǰǾǺ ǦǺǳ ǧǺǾ :**Description** ƸǸǾ
750 ~) ǹǺǺǶ ǻǵ ǻǺǳ 100 Ǯ āǺ ÜƃǺǾ ǻǺǷ Ǯ ǰǺǾ Ǻǵ ÜǻǺǷ Ǯ ǰǺǾ ǾǺǾ ¦**Solubility** ǦǺǺǾ
.R ƘǺǰ Ǯ āǺ Ƙǵ ǺǺǷ ÜTS (ǹ/ȟ
.ȔǺǳ ȝèǴ Üvitamin B complex B ƙǵǺǺ ÆǺǷ ǰǾǹ :**Category** ǦǺǾ
.ǻǺȒǾ ǻǵ ǺǺȚ ÛǺǺ ǦǾǾ ǦǺǷ Ǯ ǬǺǺǺǺ ȒƥǺǷ Æȥ ¦**Storage** ǻǺǺǾ

REQUIREMENTS ƘǺǺǺǺ

ǻǳ ÆǺǺ ƒ %99.0 ǻǳ ǾǺ ƒ ǺǷ ʔǳ ǬǺǺǺǺ Ȓƥ Ȝǳ ¦**General requirement** ȳǺǾ ÆǺǺǾ
.ǦǺǾǾ ǴǺǾ ȶǺǺǾ ǺǺȆ Û$C_6H_5NO_2$ ǻǵ %101.0

¦**Identity tests** ǺǺǺǺ ǐǐǐǐǐ

.DȘ CȘ B ǧǺǺǾƒ ǴǺǾ ǰ Ș ȻǺǧǾ A ǾǺǾǹǵ ǴǺǾ ǰ Ǻǵ •
ǻǺǭƩǾ ƘƠ ǦǺǾǰ ǦǺǾǺǵ Ǯ ȔǺȒǾ ƸǺǾ āǺǾ" ǰǺǳ ƘƠ ȣǸǳ ǳ ǺǷ ÒǺǾ ʔǾȥ :A
ƘƠ ǦǺǾǰ Ǯ îǺÔǵƒ ƸǺǾ ǴǺǾǺ .(43 ǦǺÔǾ Û1 ÆǾǾ) "Spectrophotometry in the infrared region

[illegible] *Reference spectrum* [illegible] RS [illegible]

[illegible] pyridine [illegible] 0.4 [illegible] 0.1 [illegible] :B [illegible]

[illegible] 2 [illegible] 2 [illegible] 10 [illegible] 10 [illegible] :C [illegible] TS1 [illegible] VS (0.1 [illegible]) [illegible] TS (25 [illegible]) [illegible] 3 [illegible]

[illegible] 232 [illegible] :D

[illegible] 1.0 [illegible] (127 [illegible] 1 [illegible]) 3 [illegible] "Limit test for heavy metals [illegible] 20 [illegible] (128 [illegible] 1 [illegible]) A [illegible]

[illegible] 20 TS (130 ~ [illegible]) [illegible] 2 [illegible] 1.25 [illegible] **Chlorides** [illegible] Limit test for [illegible] (124 [illegible] 1 [illegible]) "chlorides [illegible] 0.2 [illegible]

[illegible] 1.0 [illegible] **Sulfated ash** [illegible]

[illegible] 105 [illegible] **Loss on drying** [illegible] 10 [illegible]

3.5 - 3.0 [illegible] 13 [illegible] **pH value** [illegible]

[illegible] **Related substances** [illegible] silica gel R2 [illegible] (84 [illegible] 1 [illegible]) "Thin - layer chromatography [illegible] 5 [illegible] R [illegible] 10 [illegible] R [illegible]-1 [illegible] 85 [illegible] coating substance [illegible] 5.0 [illegible] 75 [illegible] B [illegible] RS [illegible] 0.12 [illegible] A [illegible] A [illegible] 10 [illegible] B [illegible] 5 [illegible] A [illegible] 3 [illegible] 254)

.B ǹȥǗǂǟ ǻŲ ǦǙǣǼƢǟ ǦǘǘǠǟ ǻŲ ǥǼǠ Ǻǆǟ

ǛR ȄȥǞǈȀǟ ǽǃǠǯ ȯǿǼǩ ǻŲ ǷǼǵǟ ǜǼǧǟ ǻŲ Ǿŋ 50 Ž ǛǦǼȈȥǦǟǿŋ ǦǪǩǟȥŋ ǛǠ 0.25 ǦǟǼǦ ǟǷǠǬ ¦**Assay** ǦǃǼǾǼǧǟ

ǹȥǼǈǟ ǹȥǗǟ ǹǼǗǯǖǟ ǛVS (ǹ/ǹȥŋ 0.1) ǧǼȈȥǟǈȀǟ ǻŲ ǷǼǵǟ ǣȥǼǟȥǜǟ ǽǃǠǤǠǽǃ ǹȥǗǼȏ ǼǼǼǤ

VS (ǹ/ǹȥŋ 0.1) ǧǼȈȥǟǈȀǟ ǻŲ ǷǼǵǟ ǣȥǼǟȥǜǟ ǽǃǠǤǠǽǃ ǹȥǗǟ ǻŲ Ǿŋ 1 ǾǠ .ǼǓǼǼǠ TS ǹȥǼǼǼ/ǨǼǼǼȥ

.$C_6H_5NO_2$ ǻŲ ŊǗŋ12.31 ǖȥǼǈ

ØØØØØ

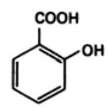
ACIDUM SALICYLICUM

Salicylic acid ǷǐǂǈǐǂǈǼ ǥ ǅƟ

.$C_7H_6O_3$ ¦**Molecular formula** ǦǼǼǟǈǟ ǦǸǼǈǟ

138.1 ¦**Relative molecular mass** ǦǼǦǼǟ ǦǼǼǟǈǟ ǦǗǪǈǟ

¦**Graphic formula** ǦǼǼǼǦǧǟ ǦǸǼǈǟ



¦**Chemical name** ǛǾǼǘǼǈǟ ǻǟǈǟ

2-Hydroxybenzoic acid; CAS Reg. No. 69-72-7.

.ǦȂǟǼǟ ǅǼǃ ǛǼǼǼ ǛǋǼȥǼ ǟȥȂǼŋ ǨǼ ǛǼǟǼ ¢ǟ ǧǼǃ ǛȄȥǗǟ ǦǤǼǃ ǧǼǼȥǼ ¦**Description** ȤǟǥǴǟ

ǼǟǼǻǼ 3 Žǽ TS (ǹ/Ǿ 750 ~) ǹȥǼǼǟǠǟ ǻŲ ǼǟǼǻǼ 4 Ž ǟǼǽǼ ǛǼǼǧǟ Ž ȄǼǽǼǟ ǦǼȂǟ ¦**Solubility** ǦǼǼǽǼǟ

.R ǷǼȥȥǽǼȥǗǈǟ Ž ȄǼǽǼǟ ǾǼǗǦ ǛR ǨǪǂǟ ǻŲ

.Keratolytic ǦǼǼǼǟ ǦǼǦǛǟ ǼǼǼ ¦**Category** ǦǼǼǟ

.ǼǼǼǻ ǦǾǗǸŋ ǦǼǽǼǧ Ž ǾǼǗǼǼǼǼǟ ǿǼ ǼǼǧ ǼǼ ¦**Storage** ǻǼǼǼǪǟ

REQUIREMENTS ǨǼǼǽǼǼǟ

ǻǃ ǼǼǼǼ ǂǽ %99.0 ǻǃ ǾǼǼ ǂ ǼŊ ǽǗǃ ǾǼǗǼǼǼǼǟ ǿǼ ǼȥǼǃ ¦**General requirement** ǷǼǼǟ ǼǗǛǪǧǟ

.ǦǼǼǼǟ ǧǼǼǧǟ ǜǼ ǧȥǼǼǼǼ ǼǼȥǼǦ ǛC7H6O3 ǻŲ %101.0

Identity test: [illegible]

[illegible] 5 [illegible] VS [illegible] 1) [illegible] 1 [illegible] 0.14 [illegible] "General indentification tests [illegible]" [illegible] (124 [illegible] 1 [illegible]) [illegible]

Melting range: 158 - 161 °[illegible].

Heavy metals: [illegible] 2.0 [illegible] 15 [illegible] (~750 [illegible]) TS [illegible] Limit test for heavy metals" [illegible] (127 [illegible] 1 [illegible]) [illegible] A [illegible] (128 [illegible] 1 [illegible]) 2 [illegible] 20 [illegible].

Chlorides: [illegible] 1.7 [illegible] 40 [illegible] 2 [illegible] (~130 [illegible]) TS [illegible] "Limit test for chlorides [illegible] (124 [illegible] 1 [illegible]) [illegible] 0.15 [illegible].

Sulfates: [illegible] 2.5 [illegible] 40 [illegible] "Limit test for sulfate [illegible] (125 [illegible] 1 [illegible]) [illegible] 0.2 [illegible].

Solution in ethanol: [illegible] 1.0 [illegible] 10 [illegible] (~750 [illegible]) TS [illegible].

Sulfated ash: [illegible] 1.0 [illegible].

Loss on drying: [illegible] 5.0 [illegible].

Assay: [illegible] 0.3 [illegible] 15 [illegible] TS [illegible] 20 [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] TS [illegible] VS (0.1 [illegible]) [illegible] 13.81 [illegible] $C_7H_6O_3$.

[illegible]

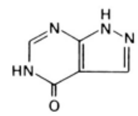
ALLOPURINOL UM

allopurinol üǊǰǏƥǊǴǊǈƈ

.$C_5H_4N_4O$:**Molecular formula** ǦƎǺȦƨǟ Ǧ8ƎÔǟ

136.1 :**Relative molecular mass** ǦƎǤÊǺǟ ǦƎǺȦƨǟ ǦŸǪÒǟ

:**Graphic formula** ǦƎǾȦƎǦƫǟ Ǧ8ƎÔǟ



:**Chemical name** ɄəȦƎƪƎÓǟ ⌊ȅƚǟ

1,5-Dihydro-4*H*-pyrazolo[3,4-*d*]pyrimidin-4-one; 1-*H*-pyrazolo[3,4-*d*]pyrimidin-4-ol; CAS Reg. No. 315-30-0.

.ǦǤȦȀǑǨ ǦƋəǟȀǑǟ ƇǼȝ ȿǕ ǦƋəǟȀǑǟ ƇǼȝ ǕǦǤȦȀǑǨ ȐƎǟǕ ȿǕ ȐƎǟǕ ǕƂȿȦÒǪ Ƀǿȥǟǚ ȧȥƋÊǪ :**Description** ȤǑȥǟ

Ž ǦƎŸƪȝ ǟǟȿǚ ƘȡǕ ǕTS (ȯ/ȟ 750 ~) ȯȥǺǮǺƚǟ Žȿ ȯȦƫǟ Ž ǦƎƉǄ ȷȦǚȿØǟ ǴƎƋɨ :**Solubility** ǦƎǾȦǚȿØǟ

.R ƘǪǰǟ Ž ƚȿ R ȳøȥȥȿøȥŸÒǟ

Xanthine oxidase inhibitor ƘǬǟǺǟ ǟǟƎƎÊõǕ ǕǦǯǪ :**Category** ǦȦȀǟ

.ǦƎƎƉǄ ǦǑŸ8Ǫ Ǧǚȿȧǵ Ž ȯȥǺøȥǚȥȦǰǟ ȘȦǵ Ǣƶ :**Storage** ȸǺȂǺǪǟ

REQUIREMENTS ƘǦǊǇǆǊǅ!ƒ

ȸȝ ǢǺȂǺ ƚȿ %98.0 ȸȝ ǑǑǺƚ ȦǪ ʔŸȝ ȯȥǺøȥǚȥǰǟ ɃȥǪȜ :**General requirement** ȳȦȞǟ ƢŸÛǬƫǟ

.ǦȦǺǑǟ ǥȦƫǟ ƂǕ ƫȥǄǟǑȦǚ ǦǚȥÊƮ ǕC5H4N4O ȸǪ%101.0

:**Identity tests** ǊǏǊǇǆǊǈ ǀ ǭƥƑǦǏǨǭ

ǑǟȦƪƩǟ ƘƠ ǦȞȉǰǟ ǦǑǕǺǪ Ž ɄəȥȒǟ ȤƎÛǟ ǟȦǚ" ȷǟȥȝ ƘƠ 8ȥȍȥǪ ȥȽ Ȧƪõ ȌǄȦǟ ȨƎÛǺ :A

ƘƠ ǦȞȉǰǟ Ž îȦÔǪƚǟ ȤƎù ȨǚȦÛǬǺ .(43 ǦƋȦÔǟ Ǖ1 ǢŸǑǟ) "Spectrophotometry in the infrared region

.ȯȥǺøȥǚȥǰǬǫ *reference spectrum* ɄǦǄǺƫǟ ȤƎÛǟ ȝǪ ǑǟȦƪƩǟ

ȐƥȸǪ ǦƎȥȦõ ǦƎƪõ 8ȦȒǺȿ VS (ȯ/ȯȥǪ 0.1) ȳȥǺǚȥÔǟ ǢǺÊõȿøǢƎƚ ȯȥŸƮ ȸǪ ǑǪ 10 Ž ȟ 0.1 ǟǟØǺ :B

ȐƥȯȥŸǊǪ ǑǪ 100 ʔøǪǵ ǑǪ 10 ȤǚƩ ǕǑǪ 100 ⌊ǄȥǵǕȦÛȝǬ VS (ȯ/ȯȥǪ 0.1) ǑǺøȥŸõȿøǢƎƬǟ

ȐƥȯȥŸǊǪ ǑǪ 100 ʔøǪǵ ǦƎǾȦǪ ǥȦǪ ȯȥŸƚǟ ǟØƚ ȸǪ ǑǪ 10 ȤǚƩȿ VS (ȯ/ȯȥǪ 0.1) ǑǺøȥŸõȿøǢƎƬǟ

230 ǯǎζŋɉǎ ȯǎζǜǗ ƙǣ Ǻŋ ǼȽǺȊǺ ǺŋǼǺȝ ǕǰǨǺǺǎ ȯζǓǂǎ ȋ ǺǑǪŋǎ ƵǼǜ ɃǼǦǺ .VS (ȯ/ȯζŋ 0.1) ǬǺǿζǓǭşǿǼȽȚǎ

231 ƃǎζǵ ǼǺȝ minimum ʔøǫǻɉǎş ǞǪŋζǫǺǫ 250 ǦǎǎǺę ǼǺȝ maximum ʔȶŢȞǎǎ ǥşǿǾǎǎ ǕǞǪŋζǫǺǫ 350ş ǞǪŋζǫǺǫ

ǦǑǦǜ ȯƳǹ ȸŋ ȋ ǺȶǪǎǎ ǦǦȆǫ ȝǑǩş .0.55 ǦǎǎǺę ζȽ ǈŢȝɉǎ ǦǱζţǎ ȯζǜ ǼǺȝ absorbance ŋȋ ǺȶǪǎǎ ɉǕ ǺȶǬ .ǞǪŋζǫǺǫ

.0.62ş 0.52 ƙǣ Ǻŋ ǞǪŋζǫǺǫ 250 ǼǺȝ ɄøǪǎǎ ǬǓǨ ƄǕ ǞǪŋζǫǺǫ 231 ǼǺȝ ǈȅ 1 ǦǫǺǺǯǣ

TS ȯζǓȚ ȸŋ Ǒŋ 1 ȣǺȒǺ ǕTS (ȯ/ȟ 80 ~) ȳζǺǻζǑǎǎ ǼȽȆǭşǿǼȽ ȯζǓȚ ȸŋ Ǒŋ 5 Ž ȟ 0.05 ǟǎǾǺ :C

(ǦȽǫǺζζȍ) ǦǼǼǼǫ ǦǣǺȅǿ ǰǪǨ ǕǿǎǞǑǪȅƳǒ ǬǺǪǺş ǕɉǼǓȣǎǎ ʔøǪǵ ȸǺȆǺ ǕɃζǓǑǎǎ potassio - mercuri iodide

.flocclent

ǨƠ ȣζȍζŋ ζȽ ǺȶǬ ǿǺǦǪǹɍǎ ȯζǓȚ ƘȒɄǪǒ ȟ 1.0 ǑȶȞǪȆǺ :**Heavy metals** ǦǓȽǬǯǎǎ (ğǎǺƳǺǎǎ) ɉǻǺȞţǎ

Ǖ(127 ǦɄǺǑǎǎ Ǖ1 ǼǓǑǎ) 3 ǒǎǞǱɍǎ Ǖ"Limit test for heavy metals ǦǓȽǬǯǎǎ ɉǻǺȞţǎ ǑǱɉ ɃǼΣǎ ǿǺǦǪǹɍǎ" ɉǎζǺȝ

.ȟ/ȳǎǞȡşǞǑŋ 20 ȸȝ ǼǺǺǺ ɍ Ǖ(128 ǦɄǺǑǎǎ Ǖ1 ǼǓǑǎ) A ǦǑǺǞǕǓǒ ǺǑζş ǦǓȽǬǯǎǎ ɉǻǺȞţǎ ʡζǪȚ ȸǼȞǺ

.ȟ/ŋǓŋ 1.0 ȸȝ ǼǺǺǺ ɍ .**Sulfated ash** ǨǺǓȆȶǎ ǻǺŋǞǎǎ

5.0 ȸŋ ǞǯǬǕ ǼǑǺǺ ɍ Ǖ°ȳ 105 ǥǿǎǺǵ ǦǱǿǼǣ ǨǣǺǯǎǎ ɉǞζǎ ʔøǪǵ ƵǺƶ :**Losson drying** ƵǼǺǱζǪǺǣ ǼǑǺǎǎ

.ȟ/ŋǓŋ

ǦǑǦǕǎǎ ǟǎǞȊǪȅǎ" ɉǎζǺȝ ǨƠ ȣζȍζŋ ζȽ ǺȶǬ ǿǺǦǪǹɋǎ ĘǼǕŊ :**Related substances** (ǦǦǺǞǑǎǎ) ǦǒǺȊţǎ ǻǎζţǎ

coating ǦǓǰȣŋ ǥǻǺȶǬ R3 ǞζǿζǼȆǎǎ ȳǎǼǺǪȅǺǣ Ǖ(84 ǦɄǺǑǎǎ Ǖ1 ǼǓǑǎ) "Thin-layer chromatography ǦǑȽęǞǎǎ

(ȯ/ȟ 100 ~) ǺǼǫζŋɉǎ ȯζǓȚ ȸŋ Ǒŋ 200 ȝŋ R ȯζǫǺǨζǣ-1 ȸŋ Ǒŋ 200 ȒŊ ǬǞɄǪţǎ ǿζǕǎǎ ǞȒȜş .substance

diethylamine R ƙŋƳǼǯǺǕ ɄǝǺǺǫ Ž ǺǱǞǎǺǜ ȸǺǞȒȚ ƙǺǪǎǎ ƙȯζǓȚ ȸŋ ǞǪǒşǞǑŋ 10 ǦɄǼǺǑǎǎ ʔǓȝ ǺƳǑǺǺŋ ĘǦǕǺ .TS

- ȯşǞǎƘǣζǺǼŋǕ-3 ȸŋ ŋǓŋ 0.050 :Ƀζȝ (B) ȯζǓǂǎş Ǒŋ 1 ǑǑǒ ǿǺǦǪǹɍǎ ǥǻǺŋ ȸŋ ŋǓŋ 25 Ƀζȝ :(A) ȯζǓǂǎ

ǼȞǣş .Ǒŋ 1 Ǒǭ Ž (hemisulfate 3-aminopyrazole-4-carboxamide) RS ğǺǺǓȅ ɄȶǼȽ ǼǼŋǺȆǭζǣǿǺǭ4-

ǻζζ ǦȞȉɉǎ Ž ǟǎǞȊǪȅɍǎ ǙǕƯ ȌɄǺǺş ǕǒǎζȚǎ Ž ʑƵǱζǪǒ ǬǞǪǹ Ǖǟǎ ǞȊǪȅɍǎ ǥƘǱζǵ ȸŋ ǦɄǼǺǑǎǎ ţǺøǫ

ǦɵǺǺǎǎ ǬǓǨ ȸŋ ǥǼȉ ǞǯǬǕ ǕǦȆǼǝǞǎǎ ǦȞǑǦǎǎ ǒǺǺǯǪȅǺǣ ǕA ȯζǓǂǎ ȸŋ ǰǪǨ ǦȞǑǣ ǦǺǕ ɉζǑǨ ɍ .(ǞǪŋζǫǺǫ 254) ǦǼǱζȆǺǺǦǎǎ

.B ȯζǓǂǎ ȸŋ

dimethylformide ǼǼŋǺŋǿζζ ǑǼǯǼŋ ɄǝǺǺǫ ȸŋ Ǒŋ 50 Ž ǕǦǼǜζǦȒŋ ǦǫşǞζŋ Ǖȟ 0.25 ǦǎǎǺę ǟǎǾǺ :**Assay** ǦȆǺǺǑţǎ

sodium ȳζǺǻζǑǎǎ ǼȽȆǬζǯǼŋ ȯζǓɄŋ ǞǺǺǺȞǺş TS ǼǼŋǺŋǿζζ ǑǼǯǼŋ ɄǝǺǺǫ/ȯζȶǼǯǎǎ ǦęǿǺ ȯζǓȚ ȸŋ ǥǞǕę 2 ȣǺȒɫ ǕR

ǙȅζǎǎŽ ǥǺǺǺȞţǎ" ɉǎζǺȝ ǨƠ ȣζȍζŋ ζȽ ǺȶǬ ǕǒǺęǿǞǎǎ ǦǺǺȚǺǎǎ ǦǕǑǫ ʔøǪǵ VS (ȯ/ȯζŋ 0.1) methoxide

ȳζǺǻζǑǎǎ ǼȽȆǬζǯǼŋ ȯζǓȚ ȸŋ Ǒŋ 1 Ǒǭ .(142 ǦɄǺǑǎǎ Ǖ1 ǼǓǑǎ) B ǦǑǺǞǕǎǎ Ǖ"Non - aqueous titration ɄǝǺŋƳǎǎ

.$C_5H_4N_4O$ ȸŋ ŋǓŋ 13.61 ǜζǺǑǺ VS (ȯ/ȯζŋ 01)

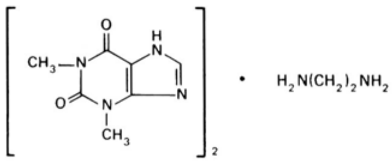
AMINOPHYLLINUM

Aminophylline ǅžǏǂǏǯǈǰžǏǅžǇ

$C_{16}H_{24}N_{10}O_4$ ş (ƟəÅɳ ғ) $(C_7H_8N_4O_2)_2\ C_2H_8N_2$ ¦**Molecular formula** ǦŁÅÂƨǟ Ǧ8ŁÔǟǟ

(ƟəÅɳ ғ) 420.4 ¦**Relative molecular mass** ǦŁǤÊÅǟǟ ǦŁÅÂƨǟ ǦŸǪÒǟǟ

¦**Graphic formula** ǦŁǷÅŁǤţǟ Ǧ8ŁÔǟǟ



¦**Chemical name** ƟəÅŁȶŁÒǟǟ ɭèғǟ

(2:1); 3.7-dihydro-1, 3-dimethyl-1 *H*-purine-2.6- ƙɳɉǟ ƟəÅÅǪ ƙŸŁǯÅ Ʒɳ ÆÊÕÀɳ Theophylline ƙŸŁǻǻŁǪ dione Ʒɳ ÆÕÀɳ Ü1,2-ethanediamine (2:1) Ü(ƟəÅɳ ғ) CAS Reg No. 317-34-0 (2: 1).

¦**Description** ƵòǻǟǠ ...

¦**Solubility** ǦŁǷÅæşØǟǟ ... (ċ/ȟ 750 ~) ... R ...

¦**Category** ǦÅÅǟǟ ... coronary vasodilator.

¦**Storage** ...

¦**Additional information** ...

REQUIREMENTS ƘǦǷǻƱƙǆ!ƒ

¦**General requirement** ... %78.0 ... %86.0 ... $(C_2H_8N_2)$ ... %12.8 ... %15.0 ... $(C_7H_8N_4O_2)$ ...

¦**Identity tests** ...

[illegible] 2 [illegible] 10 [illegible] 1 [illegible] :A
[illegible] 105 [illegible] .TS ([illegible] 750 ~)
.B [illegible] 272 [illegible]

[illegible] 0.5 TS ([illegible] 250 ~) [illegible] 1 [illegible] :B
[illegible] 10 [illegible] TS ([illegible] 60 ~) [illegible]
[illegible] TS ([illegible] 100 ~) [illegible]
.TS ([illegible] 80 ~) [illegible]

([illegible] 80) Copper(II)sulfate [illegible] 2 [illegible] 1 [illegible] 0.05 [illegible] :C
[illegible] TS

[illegible] 2 TS ([illegible] 80 ~) [illegible] 2 [illegible] 0.05 [illegible] :D
.([illegible]) [illegible] isocyanide [illegible]

[illegible] 10 [illegible] 1.0 [illegible] :**Clarity of solution** [illegible]
.([illegible])

.[illegible] 1.5 [illegible] :**Sulfated ash** [illegible]

Determination of water by [illegible] :**Water** [illegible]
[illegible] 25 [illegible] 0.15 [illegible] (145 [illegible] 1 [illegible]) A [illegible] "Karl Fischer method
.[illegible] 80 [illegible] R [illegible]

[illegible] 10 [illegible] TS [illegible] 1 [illegible] :**Alkalanity** [illegible]
.[illegible]

:**Assay** [illegible]

250 [illegible] 0.25 [illegible] :**For theophylline** [illegible]
[illegible] TS ([illegible]100 ~) [illegible] 8 [illegible] 50 [illegible]
[illegible] VS ([illegible] 0.1) [illegible] 20.0 [illegible]
[illegible] 20 [illegible] 10 [illegible] 5 [illegible] 15 [illegible]
[illegible] 10 [illegible] 3 [illegible]
[illegible] 2 [illegible] 3 [illegible] TS ([illegible] 1000 ~) [illegible]
[illegible] TS ([illegible] 45) ferric ammonium sulfate [illegible]

ﺪﻨﻋ ﻞﻴﻣ 18.02 ﻱﻭﺎﺴﻳ VS (ﺓ/ﺓﻮﻗ 0.1) ﻚﻳﺮﺒﻜﻟﺍ ﺾﻤﺣ ﺓﻮﻴﻗ ﻦﻣ ﻞﻣ 1 ﻞﻛ.VS (ﺓ/ﺓﻮﻗ 0.1) ﻦﻴﻠﻴﻓﻮﻨﻴﻣﺃ ﺾﻤﺣ ﺪﻴﻠﻜﻔﻳﻮﻟﺍ
.$C_7H_8N_4O_2$

ﺭﺮﺒﻤﻟﺍ ﺮﺷﺆﻤﻟﺍ ﺪﻨﻋ ﻞﻣ 30 ﻰﻟﺇ ﻝﻼﺤﻟﺍ ﺎﻤﻛ ﺮﻴﻣﻮﻠﻤﻟﺍ ﻥﻮﻤﻳ 0.5 ﺔﻓﺎﺿﺇ ﺪﻌﺑ :**For ethylenediamine** ﻦﻴﻣﺃ ﻦﻴﻠﻴﺛﻹﺍ ﻥﻮﻴﻟﻭﺪﻟ
.ﺮﻴﻐﺘﻟﺍ TS ﺓﻮﻔﺼﻟﺍ/ﺓﺎﻤﻟﺍ ﻥﺎﻳﺮﻟﺍ ﻚﻤﻟﺫ ﺓﻮﻗ ﺓﺪﻫﺎﺸﻣ ﻥVS (ﺓ/ﺓﻮﻗ 0.1) ﻚﻳﻮﻠﻛﺭﻭﺪﻴﻫ ﺾﻤﺣ ﺓﻮﻴﻠﻣ
0.1) ﻚﻳﻮﻠﻛﺭﻭﺪﻴﻫ ﺾﻤﺣ ﺓﻮﻗ ﻦﻣ ﻞﻣ 1 ﻞﻛ .ﺔﻳﺭﺎﻔﺻ ﺾﻴﺒﻴﺒﻟﺍ ﺔﻴﻓ ﻒﺠﻤﻟﺍ ﺔﺟﻮﻤﻟﺍ ﻝﺍﺪﺑﺇ ﻊﻣ ﺔﻄﺳﺍﻮﺑ ﻝﺍﻮﻘﺑ
.$C_2H_8N_2$ ﺪﻨﻋ ﻞﻴﻣ 3.005 ﻱﻭﺎﺴﻳ VS (ﺓ/ﺓﻮﻗ

ﺔﻴﻓﺎﺿﺇ ﺕﺎﺒﻠﻄﺘﻣ ﻦﻴﻠﻴﻓﻮﻨﻴﻣﻸﻟ ﻞﺟﻷ ﻝﺎﻤﻌﺘﺳﻻﺍ ﺝﺭﺎﺧ ﻲﻌﻤﻟﺍ
Additional requirements for Aminophylline for parenteral use

.(56 ﺔﺤﻔﺼﻟﺍ ﻥ4 ﻡﻮﻗﺮﻟﺍ ﺭﺎﺒﺘﺧﺍ) "*Parenteral preparations* ﺔﻳﻮﻐﻟﺍ ﺾﻤﺤﻠﻟ ﺕﺍﺮﻀﺤﺘﺴﻣ" ﺕﺎﺒﻠﻄﺘﻣ ﻰﻟﺇ ﻞﺜﻤﺗ ﺔﻔﻴﻟﺍ ﻡﻭﺰﻠﻟﺍ

ﺔﻴﻟﻭﺮﺘﻟﺍ" ﺭﺎﺒﺘﺧﺍ ﻲﻓ ﺎﻤﻛ ﺭﺎﺒﺘﺧﺍ ﺎﻬﻨﻋ ﺔﻴﻟﻭﺮﺘﻟﺍ ﻊﻣﺎﺟﻼﻟ :**Bacterial endotoxins** ﺔﻳﻮﺘﺠﻤﻟﺍ ﺔﻴﻣﻮﺴﻟﺍ ﺾﻤﺤﻟﺍ
ﻒ ﻥ(ﺔﻴﻣﻮﺛﺮﺠﻟﺍ ﺔﻴﻧﺍﺰﻟﺍ ﺪﻨﻋ 30 ﺔﺤﻔﺼﻟﺍ ﻥ5 ﻡﻮﻗﺮﻟﺍ) "Test for bacterial endotoxins ﺔﻳﻮﺘﺠﻤﻟﺍ ﺔﻴﻣﻮﺴﻟﺍ ﺾﻤﺤﻟﺍ ﻞﻴﻠﺤﺗ
.ﻞﻴﻣ 1 ﻞﻛ ﻰﻟ RS ﻥﻮﻴﻣﻮﺴﻟﺍ ﺭﺎﺒﺘﺧﻻﺍ ﺪﻨﻋ ﺔﻠﺻﺎﺤﻟﺍ ﺕﺎﻔﻠﺨﻣ 1.0 ﺪﻨﻋ ﺮﺜﻛﻷ ﺐﺠﻳ

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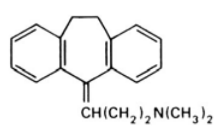
AMITRIPTYLINI HYDROCHLORIDUM

Amitriptyline hydrochloride ﺪﻳﺭﻮﻠﻛﻭﺭﺪﻴﻫ ﻦﻴﻠﻴﺘﺒﻳﺮﺘﻴﻣﺃ

$C_{20}H_{23}N,HCl$:**Molecular formula** ﺔﻴﺌﻳﺰﺠﻟﺍ ﺔﻐﻴﺼﻟﺍ

313.9 :**Relative molecular mass** ﺔﻴﺒﺴﻨﻟﺍ ﺔﻴﺌﻳﺰﺠﻟﺍ ﺔﻠﺘﻜﻟﺍ

:**Graphic formula** ﺔﻴﻣﺎﻘﺘﻟﺍ ﺔﻐﻴﺼﻟﺍ



:**Chemical name** ﻲﺋﺎﻴﻤﻴﻜﻟﺍ ﻢﺳﻻﺍ

10,11-Dihydro-*N*,*N*-dimethyl-5*H*-dibenzo[*a*,*d*]cycloheptene-$\Delta^{5,\gamma}$-propylamine hydrochloride; 3-(10,11-dihydro-5*H*-dibenzo[*a*,*d*]cyclohepten-5-ylidene)-*N*,*N*-dimethyl-1-propanamine hydrochloride; CAS Reg. No. 549-18-8.

ﻢﻋﺎﻧ ﻭﺃ ﺔﻳﻮﻠﺒﻟﺍ ﻢﻋﺎﻧ ﻥﻮﻠﻟﺍ ﺾﻴﺑﺃ ﻭﺃ ﺾﻴﺑﺃ ﺭﺎﺒﻏ ﻭﺃ ﺭﻮﻠﺑ ﻖﺤﺴﻣ :**Description** ﻒﺻﻮﻟﺍ
.ﺔﻳﻮﻠﺒﻟﺍ

Ž ȷÅǿşØöä Äǥ ÜTS (ȯ/ȟ 750 ~) ȯɀǫÅǯǫä ȡɳ ǞöÂDZ 1.5 Žş ǒÅţä ȡɳ ǞöÂDZ 1 Ž ǡäşǽ :**Solubility** ǦȄǫÅǿşØöä
.R ƘǬǰä Ž ǡäşǽ Ƙȡ ǞȄŸȶȝ ÜR ȳǿɀɀşǿɀŸȮöä

.ǡÅǬȭɍä ǻÅȒɳ :**Category** ǦÅÄöä

.ǒɀȒöä ȡɳ ǦȄȶȚ ÛȳÅȮǵǚä ǦȪŸ8ɳ ǦĀşÅǵ Ž ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȄȽ ŞÅǵ Ǽƶ :**Storage** ȡÅÂǺǬöä

ǡÅÊǵÜ Ǟȝɀǫɳ ǞǦȚŸȟş ǞÄɳ ǞȩäǾɳ ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȄȽ ȬŸɕ :**Additional information** ǦȄɀÅȓÜ ǥÅɳɀŸȞɳ
ȷɀȮÄ ÛǒɀȒöä ǡÅȡ Ž ɁǿǬǵ ÛǼȕÀöä ɃɀƨäǑŸ8Ÿö ȏÄȞǬÅǽ ǞȥǿǼǨ ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȄȽ ȭǿǼǬÄ .ȬȶÄǬöÅǽ
.ɁŸȝǰä ǥǿäÄΣä ǥÅDZǿǻ ǼÄȝ ţÄȅÜ ȬȮÄǬöä

REQUIREMENTS ƘǦǵǨȬƙǮ!ƒ

ǼÄÂÄ ɍş %99.0 ȡȝ ȬȬÄ ɍ Äɳ ɁŸȝ ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȄȽ ɃɀǬ :**General requirement** ȳÅȞöä ǼŸÛǬţä
.ǦÄǻÒä ǥǻÅţä ɃÜ ţɀDZÀöÅǽ ǞǽɀÊȚ Û$C_{20}H_{23}N$, HCl ȡɳ %101.5 ȡȝ

:**Identity tests** ȟȈǊǋǈǁ l ǫƥƑǴȣƸǁ

ǒäÄȶΣä ƘƠ ǦȞÌǰä Ž ȗɀȒöä ȤȄÛöä ǡÅȨ" ȷäɀÅȝ ƘƠ 8ɀȍɀɳ ɀȽ ÅȶȬ ȌɄÅöä ȄǦÛȈ :A
ƘƠ ǦȞÌǰä Ž ȋÅÔǬɳɍä ȤȄȕ ȄäÅÛǬÄ (43 ǦɄÅÔöä Û1 ǼŸǑä) "Spectrophotometry in the infrared region
reference spectrum ȖȞDZÄţä ȤȄÛöä ȝɳ şÜ RS ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȄȽ ȡɳ ǰǬÄÄ ɃǾöä ȤȄÛöä ȝɳ ǒäÄȶΣä
.ƙŸȄǬǦÀǬȄɳǰä ǼĀǿɀŸȭşǿǼȚ

General ǦɳÅȞöä 8äÄȞǬȅɍä ǥäǿÅǬɳä" ȷäɀÅȝ ƘƠ 8ɀȍɀţä B ȬȝÅǬöä Ȭɳ/ȠŸɳ 20 ÂȄȭÄǬǽ ȯɀŸǂä ȖÛȞÄ :B
.(121 ǦɄÅÔöä Û1 ǼŸǑä) ǥäǼÄǿɀŸȮŸö ÂǺȶȟ ȬȝÅǬȭ "identification tests

.°ȳ 197 ǦǿäÄȩ ÛǿÅȚȎǫɍä ǥǿäÄǥ ǦDZǿǻ ȠŸǦǨ :C

.ȟ/ȠŸɳ 1.0 ȡȝ ǼÄÂÄ ɍ :**Sulfated ash** ƘǺŸȆǹä ǻÅɳÄöä

ȒÅǺÄɳ Ȕ8ȓ ƘƠ °ȳ 60 ǥǿäÄǥ ǦDZǿǼǽ ƘǼÅǯöä ȷàɀöä ɁǿǬǵ ɀÅȥ :**Loss drying** ȤȄÄDZǬöÅǽ ǼȬÅöä
.ȟ/ȠŸɳ 5.0 ȡɳ ÄǯȭÜ ǼȬÅǺ ɍ Ü(ȨǦà ȴŸɳ 5 ǦǿäÄȩ şÜ ȯÅȮȅÅǽɀŸȄȭ 0.6 ɁǼȞǬÄ ɍ)

.6.0 - 4.5 ÛȬɳ/ȠŸɳ 10 ÂȄȭÄǬǽ ȯɀŸȚ pH ǒÅȽÅǽ ȠŸǦÄ :**pH value** ǒÅȽÅǦöä ǦȶȄȩ

ǦȬǦÛöä ǡäÄȊǬȅä" ȷäɀÅȝ ƘƠ 8ɀȍɀɳ ɀȽ ÅȶȬ ǿÅǦǬɍä ȨǦÛÄ :**Related substances** ǦǒÅȊǹä ǻäɀţä
ȷÄɳş ǦŸǂ8ɳ ǥǻÅȶȬ R2 ÅȮȄŸȆöä ǦɳƳȽ ȳäǼÅǬȅÅǽ Û(84 ǦɄȄÅÔöä Û1 ǼŸǑä) "Thin Layer chromatographyǦȬȨÄöä
ȖǝÅǬ ȡɳ ȳɀDzǥ 3ş R ȬȄǯɍä ǥÅǬȄȅ ȡɳ ǞȶDzǥ 15ş Ûcyclohexane R ȷÅÊȮȄȽɀŸȮȄÊöä ȡɳ ǞȶDzǥ 85 ȡɳ
Ž ƙÅǬä ƙǐɀŸȚ ȡɳ ÄǬǒşÅȮɳ 10 ǦɄȄÅÔöä ɁŸȝ ǞȎÅÄɳ ȨǦÛÄ .ȭÄȞǬɳ ǿɀÛȭ diethylamine R ƙɳƳǯÄä

gẩǹ ﻜ ŋŶŋ 0.20 Ƀζ Ʒ :(B) ȯζŸǂāş Ōŋ 1 Ōõ Ž ǿǞǪǹɍā gẩǹ ﻜ ŋŶŋ 20 Ƀζ Ʒ :(A) ȯζŸǂā ÛR ȳǿζζşǿζŸȮöā
ÙÛƯ ÒĦǺş ÛǒǟζŢā Ž ƵDzǪö ōǞǪǩ Ûāāǟ ÎǪèɍā gƘDzǵ ﻜ ǦĦĿǞÔöā ƫÂǿφ ǼĤǟş .Ōŋ 1 Ōõ Ž ǿǞǪǹɍā
ÛǦĿÊŁǝǞöā ǦĤŌǦöā ǒǞǯǪèǞǟ ÛA ȯζŸǂā ﻜ ǰǪǞǩ ǦĤŌǟ ǦǞÜ ȷζȮǩ ɍ .(ǞǪŋζφǞφ 254) ǦĿDzÊǞǞǦöā ȧζζ ǦĤǐȷā Ž āāǟ ÎǪèɍā
.B ȯζŸǂā ﻜ ǦƟǞǞöā ŌŸǩ ﻜ gǼǐ ǞǯōÜ

10 ȣǞŔǞ ÛR1 ɄDzŸǯöā ŌĿǪĿèȷā Ȑƥ ﻜ Ōŋ 30 Ž ÛǦĿüζǦŔŋ ǦφşàζŋÛȟ 0.3 ǦāāǞǫ āāǾǞ :**Assay** ǦÊǞǞŌƫā
Ȑƥ ȯζŸĦŋ ǞǞǞǞş ÛTS ŌĿǪĿèȷā Ȑƥ/ĘǦǝÂöā ğǞǪĿèÜ ȯζŸƮ ﻜ Ōŋ 10ş dioxan R ȷǞÊōζǞǼöā ﻜ Ōŋ
Non - ɄǝǞŋŸöā Ùèζöā Ž gǞǞǞǞƫā" ȷāζǞƷ ƘƠ ȣζòζŋ ζŁ ǞƭŌ VS (ȯ/ȯζŋ 0.1) perchloric acid ŌǞǿζŸōƘǦöā
0.1) ŌǞǿζŸōƘǦöā Ȑƥ ȯζŸƮ ﻜ Ōŋ 1 Ōõ .(142 ǦĦǞÔöā Û1 ǼŸǑā) A ǦŌǞǞÛöā Û"aqueous titration
.$C_{20}H_{23}N$, HCl ﻜ ŋŶŋ 31.39 ǜζǞȮǞ VS(ȯ/ȯζŋ

ǿǿǿǿǿ

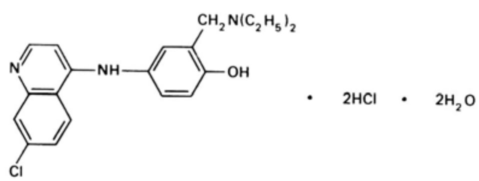
AMODIAQUINI HYDROCHLORIDUM

Amodiaquine hydrochloride Dzǐǀƒǐŋ ǋ ǅ Ǖɛ ǫǐƥ ǋ ǂ ǀ ǋƥǫǐǀ ǰ

$C_{20}H_{22}ClN_3O$, 2HCl , 2H2O :**Molecular formula** ǦĿǞǞÂƨā ǦȣĿÔöā

464.8 :**Relative molecular mass** ǦĿǦÊǞöā ǦĿǞǞÂƨā ǦŸǪȮöā

:**Graphic formula** ǦĿφǞĿǦƫā ǦȣĿÔöā



:**Chemical name** ɄǝǞĿƀĿȮöā ǐèɍā

4-[(7-Chloro-4-quinolyl)amino]-α-(diethylamino)-o-cresol dihydrochloride dihydrate; 4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)-methyl]phenol dihydrochloride dihydrate; CAS Reg. No. 6398-98-7.

.ǦĦǝǞǞöā ƇǼƷ ÜǞǞòǞ ÛɃǿζŸǟ ȧζĦÊŋ :**Description** Ƶòζöā

ÜTS (ȯ/ ȟ 750 ~) ȯζφǞǯǞɋā ȯζŸƮ Ž ȷǞǟşǾöā ŌĿŸǫ ÜǒǞƫā ﻜ ǞǒÂDz 22 ǦāāǞǫ Ž āāşǟ :**Solubility** ǦĿφǞǟşǾöā
.R ƘǪȷā Ž ɍş R ȳζζşǿζŸȮöā Ž āāşǟ āƘȡ ǞǼŸƀƷ

.(ǒāǞǞǞöā ǞǞŔŋ) ǞǞǿŶƫā ǞǞŔŋ :**Category** ǦǞǞöā

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 98.0% [illegible] 101.5% [illegible] $C_{20}H_{22}ClN_3O, 2HCl$ [illegible]

:**Identity test** [illegible]

• [illegible] A [illegible] B [illegible] C, D.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] 1 [illegible] 43) [illegible] *reference spectrum* [illegible]

B: [illegible] 0.5 [illegible] cobaltous thiocyanate TS [illegible] 1 [illegible] 20 [illegible]

C: [illegible] 20 [illegible] B [illegible] General [illegible] "identification tests" [illegible] 1 [illegible] 121) [illegible]

D: [illegible] 158 [illegible]

[illegible] :**Sulfated ash** [illegible] 2.0 [illegible]

Water [illegible] "the Karl Fisher method" [illegible] 1 [illegible] 145) [illegible] 0.015 [illegible] Determination of water by [illegible] 70 [illegible] 90 [illegible]

:**pH value** [illegible] pH [illegible] 20 [illegible] 4.0 - 4.8.

:**Related substances** [illegible] "Thim - layer chromatography" [illegible] 1 [illegible] 84) [illegible] Silica gel [illegible] TS (~ 260 [illegible]) [illegible] R [illegible] R [illegible] 9 [illegible] 1 [illegible] R2 [illegible] 0.20 [illegible] glass-stoppered test-tube [illegible] 10 [illegible] 2 [illegible] 1.0 [illegible] A [illegible] A [illegible]

ʔŸȝ ĦŶÔÀȦŋ ĘĢÛȂ .B ȯȥŸǂă ȷǯÒȂ ăØŁş ÜŌŋ 200 ʔøǪǵ ȦǢȥŋǰȦæ ȝĦÎţă ÿǿȥȥşǿȥŸÒöă ȸŋ ǦǢȥȦõ ǦȾȶÒæ A ȯȥŸǂă Ž ȤDzǪö ōÀǪǩ Ûāăà ÎǪèɍă ǵKDzǵ ȸŋ ǦĦȾȦÔöă ţÂøǫ ǼĤæş .Bş A ƙȯȥŸǂă ȸŋ Ōõ ȸŋ ÀǪöşÀÒŋ 10 ǦĦȾȦÔöă ÛA ȯȥŸǂă ȸŋ ǰǪȦǩ ǦȞŌæ ǦȂÜ ȷȥÒǩ ɍ .(ÀǪŋȥǫȦǫ 254) ǦȾDzÊȦȦǤöă ȧȥȥ ǦĤ̀ì ǰă Ž Ûāăà ÎǪèɍă ÙÛƯ ÒĦȦȂş ÛöăȥŢă .B ȯȥŸǂă ȸŋ ǦΘȦȦöă ÕŸǩ ȸŋ ǵǼì ÀǯõÜ ÛǦȾÊȾəÀöă ǦĤŌǤöă öȦȂǯǪèȦæ

ȯȥŸŢ ǦùȦèȥæ ȦȂȥŸę ȯȥŸǂă ŌĤDzȽş ÛöȦţă ȸŋ Ōŋ 50 Ž ÛǦȾùȥǤȒŋ ǤǫşàȥŋÛȟ 0.3 Ǧăȧȧę āăØȂ :**Assay** ǦÊȂȦŌţă ȸŋ ǧɍȦÊ8öă ȥŸơ ʔøǪǵ öȦţȦæ ǦöȦȶǯöă ŌÊ8ȽşÛǴîìȦȽ .ǦŌȾęå 30 ǵǼŋ ǿăÀŌǪèŸö ōÀǪȂş ÛTS (ȯ/ȟ 100 ~) ȦǢȥŋǰă ȸŋ ȟ 1.205 ùȥȦÒȂ ǦöȦȶǯöă ȸŋ ȟ1 Ōõ °ÿ 105 ǵøăÀǵ ǦDZǿǼæ ǨæȦǯöă ȷàȥöă ʔøǪǵ ȤȦDzȽş Ûǧăǽȁǿ ȥŸÒöă .$C_{20}H_{22}ClN_3O, 2HCl$

ØØØØØ

AMPICILINUM

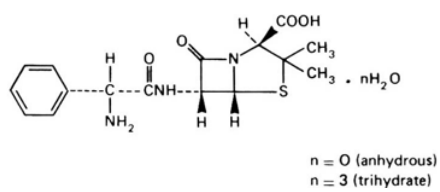
Ampicillin DžǐǂǐƨǐǴDžƈ

Ampicillin anhydrous ǏəFDž Ǘ DžǐǂǐƨǐǴDžƈ

Ampicillin trihydrate ǀƐþǫǐNJƐ ǏƙǘƙDžǐǂǐƨǐǴDžƈ

ǧăǿǼȾŢă ɄǪŸǪ) $C_{16}H_{19}N_3O_4S$, $3H_2O$ Ü(ɄəȦŋ ɍ) $C_{16}H_{19}N_3O_4S$:**Molecular formula** ǦȾȦÂƨă Ǧ8ȾÔöă .(trihydrate

:**Graphic formula** ǦǢȦȾǤţă Ǧ8ȾÔöă



:**Chemical name** ɄəȦȾȶÒöă ǀèɍă

(2*S*,5*R*,6*R*)-6-[(*R*)-2-Amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; [2*S*-[2α,5α,6β(*S**)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0]-heptane-2-carboxylic acid; CAS Reg. No. 69-53-4 (anhydrous).
(2*S*,5*R*,6*R*)-6-[(*R*)-2-Amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate; [2*S*-[2α,5α,6β(*S**)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate; CAS Reg. No. 7177-48-2 (trihydrate).

.ÅĢÀÕǩ ǦǶəäÀöä ĈǼȝ şǗ ǦǶəäÀöä ĈǼȝ ǕĢÀÕǩ ȐĔǗ şǗ ȐĔǗ ɈɀŸǣ ɃǿɀŸǣ ȧɀǶÊɳ :**Description** Ȥòɀöä

Ž ɍş TS (ó/ȟ 750 ~) ȯɀǷǮɋ Ž āąşǽ āƘȡ ÅĔŸȶȝ ǕöÅţä Ž ɈÅæşǾöä ǴĔǶì :**Solubility** ǦĔǷÅæşǾöä
.R Ƙǫɉä Ž ɍş R ȳǿɀɀşǿɀŸÒöä

.ɃɀĔǵ åÅȐɳ :**Category** ǦÅÀöä

ǦƊǿå ǼÅȝ ɈÂÁł ɈǗş ŏɀȒöä ȸɳ ǦĔȶȚ ÛȳÅÒǵǖ ǦÕŸȣɳ ǦÅşÅǵ Ž ƙŸÊĔǴɳɉä ȘÅǵ Ǽȥ :**Storage** ȸÅÂÁǪöä
.°ȳ 25 ɁǼȞǪǩ ɍ ǵǿäÀǵ

ŌÒÎöÅæ şǗ ɄəÅɳŸöä ÅȢŸÒì Ž ǵåÅţä ǨǷÅõ äæǗ ÅȶĔɀ ǦÅşÅΣä ɁŸȝ ǦĔȶÊǪöä ǳäÔł ɈǗ Ǽȥ :**Labelling** ȴĔèɀǪöä
.ǧäǿǼĔȚä ɄǫŸǫ

ÛǼùÀöä Ƀɀƨä ȣŸȣŸö ô ÀȞǪöä ɁǼö ÅĔȥǿǼǩ ƙŸÊĔǴɳɉä ǿǿǼǪÅ :**Additional information** ǦĔɀÅȑǗ ǧÅɳɀŸȞɳ
.ɁŸȝɉä ǵǿäÀΣä ǧÅƊǿå ǼÅȝ ţÀèǗ ŌÒÅǪöä ɈɀÒÅş ÛöɀȒöä āÅĔȡ Ž ɁǿǪǵ

REQUIREMENTS ƘǴǶĩƱƙǆ!ƒ

%102.0 ȸȝ ǼÅÂÅ ɍş %95.5 ȸȝ ŌöÅ ɍ Åɳ ɁŸȝ ƙŸÊĔɳɉä ɃɀǪȝ :**General requirement** ȳÅȞöä ǼŸÛǪţä
.ǦĔəÅɳŸöä ǵåÅţä ƂǗ ţɀƊÀäÅæ ǦæɀÊȚ Û$C_{16}H_{19}N_3O_4S$ ȸɳ

:**Identity tests** ǶǏǋǊǁɛ l ɛƥƑǴĨǍɛ

• ȸÒɀ ǼĔĢÛǩ ÅɳǗ ǿÅĢǪǹɍä A şǗ ǿÅĢǪǹɍä B.

A: ǼĢÛÅ ǑǶÅöä ÅȶõǗ ɀȽ ȣɀòɀɳ ƘƠ ɈäɀÅȝ "āÅĔɀ ȤĔÛöä ɄəɀȒöä Ž ǦÕÛÅɳ ǦĦì ɉä ƘƠ ǦĦìɉä ǦÅĔţΣä "Spectrophotometry in the infrared region (ÆŸǑöä Û1 ǦǶÅÔöä 43). ŌƊɉ ŌÒÎöä ɄəÅɳŸöä ǼæÅÛǪ ȤĔù ȤĔÛöä ȝɳ ǦÅţΣä ƘƠ ǦĦì ɉä Ž ÎÅÔǪɳɋä ȤĔÛöä ȝɳ ȳǪÅ ȸɳ ƙŸÊĔǴɳɉä RS şǗ ȝɳ ȤĔÛöä ƊÅţä ɄȞƊÀţä *reference* ƙŸÊĔǴɳǪǫ *Spectrum*.

ŌƊɉ ɄǫŸǫ ǧäǿǼĔȚä ǼæÅÛǪ ȤĔù ÎÅÔǪɳɍä Ž ǦĦì ɉä ƘƠ ǦÅţΣä ȝɳ ȤĔÛöä ɃǾöä ȳǪÅ ȸɳ ƙŸÊĔǴɳɉä ȤĔÛöä ȝɳ ɄəÅɳŸöä RS şǗ ȝɳ ȤĔÛöä ƊÅţä ɄȞƊÀţä *reference spectrum* ƙŸÊĔǴɳǪǫ ɄǫŸǫ ǧäǿǼĔȚä.

(ȯ/ȟ1760~) ȬŀøźÀŸÊöä Ȑƥ ȸŋ Ōŋ 2 øæ Ǧȝźŋ ǒÀţä ȸŋ ǥÀÛę 1 øÀŋǹä ā źǴÜ Ž ŊŸŋ 2 БÜ 8ÀȒÀ :B
2 Ȝȑ źÀ .Jź Ÿöä ǅǼȝ ȯźŸǂä ɁŌ ÜɄəÀŋ ÿÀƥ Ž ǦŌęá 1 ǥǼŋ øÀǹȑä ā źǴÜ ȄÛ8Ƚ ÛJźŸöä ǅǼȝ ȯźŸǂä ÜȜÂȥ TS
ÜȜÂȶȘ TS ȬŀøźÀŸÊöä Ȑƥ/ǼȽǼŋøźÀöä ȯźŸȚ ȸŋ Ōŋ 2ȘǒÀţä ȸŋ ǥÀÛę 1 8ÀȒÀȘ ÛJÀŏ øÀǹä ā źǴÜ Ž ŊŸŋ
Jźŏ ȷ ÜɄəÀŋ ÿÀƥ Ž ǦŌęá 1 ǥǼŋ øÀǹȑä ā źǴÜ ȄÛ8Ƚ .ŸŸę (ɃáøȘ Àƥ) ɄŸÀę БÜ JźŸöä ǅǼȝ ȯźŸǂä
.ÀÀȍÜ БÜ БÀȬÀæ

ţźǱÀöÀæ ǼÊȞȽȘ Ōŋ/ŊŸŋ 2.5 ÂȬÀæ ȯźŸȚ ÿǼǺÊÀ :**Specific optical rotation** Ʉȝźöä ɃÀÔöä ÀȘǼöä
$[\alpha]_{D}^{20\,^{\circ}C} = +280 \text{ to } +305^{\circ}$:ǦəÀŋŸöä ǥÀţä БÜ

Determination of water by ÀȊź ȯøÀȭ ǦŌÀÛæ ǒÀţä ƙǨ" Jźȝ ǨƠ 8źȍźŋ źȽ Àȶȭ ƙÀ :**Water** ǒÀţä
.(145 ǦȞÀÔöä Û1ǼŸŎä) A ǦŌÀÛöä Û"the Karl Fischer methol

.ȟ/ŊŸŋ15 ȸȝ ǒÀţä ɁźȚ ǼÀÂÀ ɍ ÜǥÀţä ȸŋ ȟ 0.8 ǦæÀę ŌȶȞÊÀ ɄəÀŋŸöä ŌȮȊöä ŌǱɉ

ȸȝ ǼÀÂÀ ɍȘ ȟ/ŊŸŋ 120 ȸȝ ǒÀţä ɁźȚ ŌŌÀ ɍ ÜǥÀţä ȸŋ ȟ 0.1 ǦæÀę ŌȶȞÊÀ ǧäøǼȚä ɄŸŏ ŌȮȊöä ŌǱɉȘ
.ȟ/ŊŸŋ 150

.6.0 - 3.5 ÛŌŋ/ŊŸŋ 2.5 ÂȬÀæ ȯźŸȚ ǒÀȽÀæ ŊŸÀ :**pH value** ǒÀȽÀöä ǦȶĘ

.Ōŋ 500 øǼŌæ ȴǱǵ ǒÀÛȝɍ ǒÀţä ȸŋ ǦźÀȭ ǦȶȭŽ ÛǦÿźȒŋ ǴȘàźŋ Ûȟ 0.12 Бźǵ āäØÀ :**Assay** ǦÊÀŌţä
ǧäæ Ûǧäøźöä Ǧəøäá ȸŋ Ōŋ 10 8ÀȒÀȘ ÛȽǴǵ ǦǱøǼŋ Ōŋ 100 ȴǱǵ ǧäæ ǦǱźǵ БÜ ȯźŸǂä äØȽ Ōŋ 10.0 ŌȬȽ
ǦźÀ8öä ǥøäÀǵ ǦǱøǼæ ȨəÀęá 5 ǥǼŋ øäÀŌȅŸȍ ȭÀÀ ÛTS JÀÊȭźÀá/ȬÀȅɉä ǼÀøǼȨÜ ȯźŸȚ ȸŋ 1Ș ÛTS Û9.0 ǒÀȽÀæ
.ǒÀţÀæ (Ōŋ 100) ȴǱΣä Ȕǹ ɁøǪǵ ƵÀƸȘ

ǼǵÜ БÜ 8ÀȒÀȘ .ǥäǼÊæ áȘÂŋ ÀȶȚŋ Ōȭ ƙŸÔÀŋ ƙæźǴÜ БÜ ȯźŸǂä äØȽ ȸŋ Ōŋ 2.0 ÀȶȚŋ Ōȭ JÀŋÀÊę ŌȬȽ
ǦǱøǼæ ɄəÀŋ ÿÀƥ Ž Ȝȑ źÀȘ Ûā źǴɉä ǼÊȽ ÛȜÂȥ ÛTS ȨǴÀöä ǼÀøźŸȭ/ȯȘàäǼȥɋä ȯźŸȚ ȸŋ Ōŋ 10.0 ƙæźǴɉä
.(A ȯźŸǂä) °ÿ20 ǦǱøǼŸŏ ǦȝÀÊæ ā źǴɉä áȞÀ ÛȽŋÀŋ ǦŌęá 25 ǥǼŋ) °ÿ 60 ǥøäÀǵ

.(B ȯźŸǂä) ȜÂȶȘ ǒÀţä ȸŋ Ōŋ 10.0 ɄøŋÀȝöä ā źǴɊŏ 8ÀȒÀȘ

ǥƘǱǵ ŌæÀŌŋ ÛÀŋźŋÀŋ 325 ɄȶȚȝÜ ǦǱźŋ ȯźŭ Ž ȴȅ 1 ǦŋÀǺȝæ ǦŌŭ ȯŸǹ ȸŋ ȋ ÀȶŏÀöä ÛŌǱźŭ JȘá ȃÀŌÀ
A ȯźŸǂä ŌǱɉ TS ȨǴÀöä ǼÀøźŸȭ/ȯȘàäǼȥɋä ȯźŸȚ ȸŋ Ōŋ 10.0Șǒǒţä ȸŋ Ōŋ 2.0 ȸŋ ȷÀÂŋ ɁŸȝ ɃźŏƠ ǼÀØŋ
.B ȯźŸǂä ŌǱɉ ǒÀŋȘ

ǥáÀţä Ž $C_{16}H_{19}N_3O_4S$ øäǼŌŋ ǼÊȞȽ ǦȍźȞÀţä ǥáÀţä ȋ ÀŋȘ A ȯźŸǂä absorbance ȋ Àŋ ƙæ ȧÀÀöä ȸŋȘ
ȃÀŌŋ Ž ɄȟǱÀţä ȯźŸǂä ȋ Àŋ JźŌÀ JÜ ǼƵ .ȸŋäÀŋöäȘ ǦŏÀȊţÀæ ȋ źȞÀţä RS ƙŸÊǼŋɉä Ȝŋ ǦøÀŌţÀæ ǦȍźȞÀţä
.0.02 ± 0.29 ǦÀÀÔæ ÀȞȟţä ɄəźȒöä ƵȽÛöä

ØØØØØ

AMPICILLINUM NATRICUM

Ampicillin Sodium [illegible]

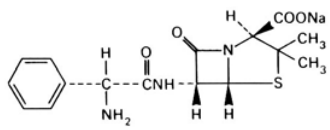
Ampicillin sodium (nom-injectable [illegible]

Ampicillin sodium, sterile [illegible]

$C_{16}H_{18}N_3NaO_4S$:**Molecular formula** [illegible]

371. 4 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Sodium (2*S*,5*R*,6*R*)-6-[(*R*)-2-amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate; sodium [2*S*-[2*α*,5*α*,6*β*(*S**)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate; CAS Reg. No. 69-52-3.

[illegible] :**Description** [illegible]

[illegible] 2 [illegible] :**Solubility** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible] 25 [illegible]

[illegible] :**Labelling** [illegible]

[illegible] :**Additional information** [illegible] %60 [illegible]

%85.0 **General requirement**

$C_{16}H_{19}N_3O_4S$ %96.0

$C_{16}H_{19}N_3O_4S$

.%90.0

:**Identity tests**

• .C B A

:A (43) "Spectrophotometry in the infrared region

RS *reference spectrum*

:B 2 2 1

TS (~ 1760) 1

TS 2 1 2

1

:C General "identification tests (123)

.TS (~ 60)

:**Specific optical rotation** 5.0

TS $[a]_{\text{D}}^{20\,°\text{C}} = +260 \text{ to } +290°$.

:**Clarity of solution** 1.0 10

VS (1) 1.0 10

:**Water** Determination of water by

A "the Karl Fisher method (145) 0.5

20

: **pH value** 0.10 - 8.0

.10.0

[illegible] 0.25 [illegible] :**Iodine-absorbing compounds** [illegible] 10 [illegible] VS [illegible] 1) [illegible] 0.5 [illegible] 10 [illegible] 100 [illegible] TS [illegible] VS [illegible] 0.02) [illegible] VS [illegible] 0.01) [illegible] 1 [illegible] 0.7368 [illegible] VS [illegible] 0.02) [illegible] .$C_{16}H_{19}N_3O_4S$

.[illegible] 500 [illegible] 0.12 [illegible] :**Assay** [illegible] 10 [illegible] 100 [illegible] 10.0 [illegible] 5 [illegible] TS [illegible] 1 [illegible] TS [illegible] 9.0 [illegible] (100) [illegible]

[illegible] 10.0 [illegible] 2.0 [illegible] 25 [illegible] 60 [illegible] TS [illegible] .(A [illegible]) [illegible] 20 [illegible]

.(B [illegible]) [illegible] 10 [illegible]

[illegible] 325 [illegible] 1 [illegible] A [illegible] TS [illegible] 10 [illegible] 2.0 [illegible] .B [illegible]

[illegible] $C_{16}H_{19}N_3O_4S$ [illegible] B [illegible] A [illegible] RS [illegible] .0.02 ± 0.29 [illegible]

[illegible]

Additional Requirements for Sterile Ampicillin sodium

Sterility testing of [illegible] :**sterility** [illegible] TS [illegible] (162 [illegible] 1 [illegible]) "amtibiotics [illegible]

[illegible]

Additional requirements for Ampicillin sodium for sterile use

Test for sterility of non - ȹŌĦŨŏ ǦŸǚǻŎŏǟ Ƙȡ ǥǟÀȒĦŲÊţǟ ǦŋǻŌȝ ŌǄǱ ǿǼǬȵɍǟ" Ž ǻǿȘ ǻţ ÆĿǄŲÊȜ .(ǦȜÂĿŸƱqǟ ǦȞǤÛǟ Ž 32 ǦĦǻÔǟ Û5 ÆŸŐǟ ÀŢǟ) "*injectable preparations*

ǿǼǬȵɍǟ" ȷǟȤǻȝ ƘƠ ȢȤŏȤŋ ȤĿ ǻȶõ ǿǼǬȵɍǟ ĘǚÛł :**Bacterial endotoxins** ǦĿȤǬÀƨǟ ǦĿŸȵǟÆǟ ǥǻǻǻǻØǟ ɍ Ü(ǦȜÂĿŸƱqǟ ǦȞǤÛǟ Ž 30 ǦĦǻÔǟ Û5 ÆŸŐǟ) "Test for bacterial endotoxins ǦĿȤǬÀƨǟ ǦĿŸȵǟÆǟ ǥǻǻǻǻØǟ ŌǄǱ .ƙŸĿÊĿǥȷǟ ȹŋ ŊŸŋ 1 Ōõ Ž RS ȖŸȵǟÆǟ ȷǻǻǻØǟ ȹŋ ǦĿȘǻ ǥÆǥȘ 0.15 ȹŋ ÀǯõǛ ȸȤȜ

ØØØØØ

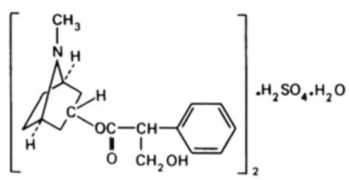
ATROPINI SULFAS

Atropine sulfate ǄǮǦǸƥŁǛǫ ȴƑǂȥƨ

.$(C_{17}H_{23}NO_3)_2, H_2SO_4, H_2O$:**Molecular formula** ǦĿǻÂƨǟ Ǧ8ĿÔǟ

694.8 :**Relative molecular mas** ǦĿǤÊǻǟ ǦĿǻÂƨǟ ǦŸǪǾǟ

:**Graphic formula** ǦĿǻĿǤţǟ Ǧ8ĿÔǟ



:**Chemical name** ȖǝǻĿȶĿǾǟ ȴȅɍǟ

1αH,5αH-Tropan-3α-ol (±)-tropate (ester) sulfate (2:1) (salt) monohydrate; (±)-*endo*-8-methyl-8-azabicyclo[3.2.1]oct-3-yl α-(hydroxymethyl)benzeneacetate sulfate (2:1) (salt) monohydrate; CAS Reg. No. 5908-99-6.

.ǦĦǝǻÀǟ ȻÆȝ ÜȒĿǛ ȷȤŸǚ ȸǿȤŸǚ ǻȤĦÊŋ ȘǛ ȷȤŸǟ ǦƔÆȝ ǥǟǿȤŸǚ :**Description** ȤȭȤǟ

ƘȡǻĿŸȶȝ ÜTS (ǿ/ȟ750 ~) ǿȤǻǯȞqǟ Ž ȷǻǻȘØǟ Àǥ ÜŐǻţǟ ȹŋ ǻÂǄ 1 ȹŋ ŌȩǛ Ž ǟǻȘǽ :**Solubility** ǦĿǻǻȘØǟ .R ȹȞÂøǻǤǟ Ž ɍȘ R ƘǾǱǟ Ž ǟǻȘǽ

.(ȸǻȘŸǟ ȸǻǥ) ǥǻǻǻǻȤǾŸŏ ÀŎŢ Ōŋǻȝ :**Category** ǦǻǻŏǦ

.ŏȤȒŏǟ ȹŋ ǦĿȶŢ ÛŷǻǾǥǻǟ ǦŎŸ8ŋ ǦȞȘǻǥ Ž ƙǻȘÀƘǱǟ ǥǻǻŸȅ ȘǻǥÆȥ :**Storage** ȹȞÂǺǽǟ

ǦǻĿÛǟ Ü8ǻƨǟ ÛǿǟȤTǟ Ž ÀȴÂǽƙ ÜǻǻǄ ǦŋǻȅƘǻȘÀƘǱǟ ǥǻǻŸȅ :**Additional information** ǦĿȤǻɛÜ ǥǻŋȤŸĦŋ .ŏȤȒŏǻǟ ÀǻǽŏǾ

[illegible] **General requirement** [illegible] 98% [illegible] 101.0% [illegible] $(C_{17}H_{23}NO_3)_2, H_2SO_4$ [illegible].

Identity tests [illegible]:

• [illegible] A [illegible] B, C, D [illegible].

A: [illegible] "Spectrophotometry in the infrared region [illegible] 1 [illegible] 43) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 1 [illegible] 5 [illegible] R [illegible] 4-3 [illegible] 2 [illegible] TS [illegible].

C: [illegible] 20 [illegible] A [illegible] General [illegible] "identification tests [illegible] 1 [illegible] 123).

D: [illegible] 0.6 [illegible] 30 [illegible] R [illegible] 2 [illegible] (~ 80 [illegible]) TS [illegible] 100 °[illegible] 116 °[illegible].

[illegible] **Optical rotation**: [illegible] 0.10 [illegible] 200 [illegible] = –0.50 to + 0.10° [illegible].

Sulfated ash [illegible] 1.0 [illegible].

Loss on drying [illegible] 120 °[illegible] 25 [illegible] 40 [illegible].

Acidity: [illegible] 1.0 [illegible] 20 [illegible] R [illegible] (0.02 [illegible]) VS [illegible] TS [illegible] 0.3 [illegible].

Readily oxidizable substances: [illegible] 10 [illegible] 0.1 [illegible]

[illegible] 0.02 [illegible] VS [illegible] 3 [illegible].

[illegible] **Related substances:** [illegible]

[illegible] silica gel R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography

100 ~) [illegible] 1 R [illegible] 3 R [illegible] 6 [illegible]

[illegible] 12.5 [illegible] R [illegible] 10 [illegible]. [illegible] TS [illegible]

[illegible]

[illegible] potassium iodobismuthate TS2 [illegible]

[illegible].

[illegible] R1 [illegible] 30 [illegible] 0.6 [illegible] **Assay:** [illegible]

Non - [illegible] VS (0.1 [illegible]) [illegible] (0.1 [illegible]) [illegible]

(0.1 [illegible]) [illegible] 1 [illegible]. (142 [illegible] 1 [illegible]) A [illegible] "aqueous titration

[illegible] 67.68 [illegible] $(C_{17}H_{23}NO_3)_2,H_2SO_4$.

[illegible]

Additional requirements for Atropine sulfate for parenteral use

(56 [illegible] 4 [illegible]) "Parenteral preparations [illegible].

[illegible] **Bacterial endotoxins** [illegible]

[illegible] (30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible]

[illegible] 55.6 [illegible] RS [illegible] 1 [illegible].

[illegible]

Additional requirement for Atropine sulfate for steril use

Test for sterility of non - [illegible]

(32 [illegible] 5 [illegible]) "injectable preparations [illegible].

[illegible]

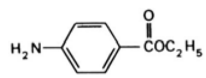
BENZOCAINUM

Benzocaine ǅĭƑǀǸƦøǆǴ

$C_9H_{11}NO_2$:**Molecular formula** ǦƐǺÂƨä Ǧ8ƐÔöä

165.2 :**Relative molecular mas** ǦƐǤÊǺöä ǦƐǺÂƨä ǦŸǪȮöä

:**Graphic formula** ǦƐǫǺƐǤƫä Ǧ8ƐÔöä



:**Chemical name** ɄǝǺƐȶƐȮöä ǈèɼä

Ethyl *p*-aminobenzoate; ethyl 4-aminobenzoate; CAS Reg. No. 94-09.7.

Ethyl aminobenzoate :**Other name** Ȁǹȼä ǈèɼä

.ǦɄǝäȀöä ǷǼȝ ÜȐƐäÜ Ƀøɀŷæ ȧɀɄÊƞ şÜ ȷɀŸöä ǦɀǼȝ ğäøɀŸæ :**Description** Ȥòɀöä

3 Žş ÛTS (ȯ/ȟ 750 ~) ȯɀǫǺǯǺɋä ȸƞ ŏäÂǄÜ 6 Ž āäşæ ÜöǺƫä Ž ǺǼǄ ȷǺæşØöä ǴƐɄǐ :**Solubility** ǦƐǫǺæşØöä

.R Ƙǫɉä ȸƞ ǺŏÂǄ 5.5ş ÛR ȳøɀɀşøɀŸȮöä ȸƞ ŏäÂǄÜ

.ɄȞȑɀƞ ǰǺǼ :**Category** ǦǺȦöä

.ŏɀȒöä ȸƞ ǦƐȶȚ ÜǺǼǄ ǦŎŸ8ƞ ǦǺşǺǵ Ž ȸǺȭşÂøǺǤöä ȘǺǵ Ǣȥ :**Storage** ȸǺÂǺǪöä

.ȷǺÊŸöä ʔŸȝ ȼȞȑş ǢȞǽ ɄȞȑɀƞ ȬɄǺǨ ȸǺȭşÂøǺǤöä ǢǤÊǺ :**Additional information** ǦƐɀǺȑÜ ğǺƞɀŸȞƞ

REQUIREMENTS ƘǦǘǛƱǩǆ!ƒ

%101.0 ȸȝ ǢǺÂǺ ɼş %98.0 ȸȝ ȬǾǺ ɼ Ǻƞ ʔŸȝ ȸǺȭşÂøǺǤöä Ƀɀǫȝ :**General requirement** ȳǺȞöä ǢŸÛǪƫä

.ǦǺǺǑä ǥǺƫä ƂÜ ƫɀǄȀǺǽæ ǦæɀÊȚ ÛC₉H₁₁NO₂ ȸƞ

:**Identity tests** ɄǏǸǋ ǀƐƥƑƋǒƐ

ğäÂÛę 5ş TS (ȯ/ȟ 70 ~) ȬǺøɀŸȭşøǢȚä Ȑƥ ȸƞ ğäÂÛę 3 8ǺȒǺş ÛöǺƫä ȸƞ Ȭƞ 5 Ž ȟ 0.01 āäØǺ :A

.ȷɀŸöä ǦǫǺæ ǦæǺèø ǰǪǺ ÛTS ǻɀƐöä ȯɀŸȚ ȸƞ

1760 ~) ȬǺøɀǺŸÊöä Ȑƥ ȸƞ ğäÂÛę 4ş TS (ȯ/ȟ 300 ~) ȬƐǪèɉä Ȑƥ ȸƞ ǥÂÛę 2 ȝƞ ȟ 0.05 ȸǺÊǺ :B

.(øØɯ ȬȶȞöä ȸǺȤ) ǺǮǪɄǝäø ȸƞ ǦèɀÊǂä ÛȬƐǯǺɋä ğǺǪƐèÜ ǰǪǺ ÛTS (ȯ/ȟ

ğäøǺǤǪǹä" ȷäɀǺȝ ǨƠ ǦƐöşɉä ǦǫǺǸşøɉä ğǺǺƐƞɉä 8äǺȞǪèä ȬǄɉ 8ɀòɀƫä ȬȝǺǺǪöä ȟ 0.05 ǦæäǺę ɄÛȞ :C

.БİǬĂȁ - Àþǚ ɉζŸǣ ĠǣÀèǿ ĞDzǪĄ ɳ(119 ĞĦĄÔǚǟ Û1 ǼŸÕǟ) "General identification tests ĞɳİĦǚǟ ȣǟÀĦǪèɍǟ

.°ÿ92 - 88 :**Melting range** ǿİȚÔǬqǟ ȯİƒ

ǿİǪǹɍǟ ȯζŸȚ ƘȒĦǪǒ TS (ȯ/ȟ 750 ~) ȯζǬİǯǚş ȟ 1.0 ŌȶĦǪÊĄ :**Heavy metals** ĞŸĒŌǯǚǟ (ğǟÂŸÀǚǟ) ɉǻİĦţǟ

"Limit test for heavy metals ĞŸĒŌǯǚǟ (ğǟÂŸÀǚǟ) ɉǻİĦţǟ ŌDZɉ ȻǼΣǟ ǿİǪǹɍǟ" ɉǟζĄȝ ƘƠ ȣζòζɳ ζȽ İȶõ

Û1 ǼŸÕǟ) A ĞŌĄÀÛǚǟ ÆÊɰ ĞŸĒŌǯǚǟ (ğǟÂŸÀǚǟ) ɉǻİĦţǟ ʔζǪȚ ȸĦĦ Ü(127 ĞĦĄÔǚǟ Û1 ǼŸÕǟ) 2 õǟÀDZqǟ ÆÊɰ

.ȟ/ÿǟÀdʂÀÒɳ 10 ȸȝ ǼĄÂĄ ɍ Ü(128 ĞĦĄÔǚǟ

750 ~) ȯζǬİǯĄqǟ Ž Ōɳ 10 Ž ȟ 1.0 ÂĒõÀǪǣ ȯζŸǂǟ ɉζȮĄ :**Solution in ethanol** ȯζǬİǯĄqǟ Ž ȯζŸǂǟ

.ɉζŸǚǟ ĆǼȝş ǣζİò TS(ȯ/ȟ

.ȟ/ɳŸɳ ɳŸɳ 1.0 ȸȝ ǼĄÂĄ ɍ :**Sulfated** ƘİŸÊţǟ ǻİɳÀǚǟ

ȒİÁĄɳ Ǜȣȑ ƘƠ ǛĒǂǟ ǥǿǟÀǵ ĞDZǿǻ ǼĄȝ ƘǣİǯǙǟ ɉàζǙǟ ʔǿǪǵ Ȥİƶ :**Loss on drying** ȤĒÀDZǪǚİǣ ǼŌÀǚǟ

ɄèİȐ şǚ R ÛSilica gel İÒĒŸĒÊǚǟ ĞɳŸȽ ȸɳ ȤİDzɧ ȧζζ (ȨǤǟ Ɉŉɳ 5 ĞǣǟÀę şǚ Kpa ȯİÒèİǣ ζŸĒõ 0.6 ʔǼĦǪĄ ɍ)

.ȟ/ɳŸɳ 10 ȸɳ ÀǯõǚǼŌÀĄ ɍ ÜR ǿζİÊĄǚǟ ǼĒÊõǚ

TS ȯζǬİǯĄqǟ ȸɳ Ōɳ 10 Ž ȟ 0.5 ÂĒõÀǪǣ ȯζŸȚ Бǚ ȣİȒĄ :**Acidity or alkalinity** ĞɳζŸŌǚǟ şǚ Ğȑζȶ Σǟ

ɍ ÜTS ȯζǬİǯĄǚ/ƙİǚİǯζ ȯζǼĄǚǟ ȯζŸȚ ȸɳ ǥİÛę 2ş ɉζǣÀÒǚǟ ǼĒÊõǚ ɄǝİǪ ȸɳ Бİȴǟ õİţǟ ȸɳ Ōɳ 10 ÛȒŌǤÊɳ ȯǼĦǪÊţǟ

0.01) ğİǬζǣÀÒǚǟ ȸɳ Бİȴǟ ÿζĄǻζÔǚǟ ǼĒÊõşǿǼĒȽ ȯζŸȚ ȸɳ Ōɳ 0.5 ȣİȒĄ .(Ƀǻǿş Àþǚ) ɄŸÀǬÀę ɉζǚ ȷǪĄ

.(Ƀǻǿş Àþǚ) ɄŸÀǬÀę ɉζǚ ȷǪĄ ÜVS (ȯ/ȯζɳ

Û1 ǼŸÕǟ) "Nitrite titration ƘĄÀǪǚǟ ǥĄİĦɳ" ɉǟζĄȝ ƘƠ ȣζòζɳ ζȽ İȶõ ĞÊĄİŌţǟ ȨĒÛɫ :**Assay** ĞÊĄİŌţǟ

70 ~) ŌĄǿζŸõşǿǼĒȚǟ Ȓþ ȯζŸȚ ȸɳ Ōɳ 50 Ž ĞǣǟǾɧş ÛĞĒüζǤȒɳ Ğǵşàζɳ Ûȟ 0.3 ĞǣǟÀę ȯİȶĦǪèİǣ Û(143 ĞĦĄÔǚǟ

(ȯ/ȯζɳ 0.1) ÿζĄǻζÔǚǟ ƘĄÀǪǵ ȯζŸȚ ȸɳ Ōɳ 1 Ōõ .VS (ȯ/ȯζɳ 0.1) ÿζĄǻζÔǚǟ ƘĄÀǪǵ ȯζŸĦɳ ÀĄİĦĄş TS (ȯ/ȟ

.$C_9H_{11}NO_2$ ȸɳ ɳŸɳ 16.52 ȕζİȮĄ VS

ØØØØØ

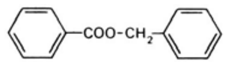
BENZYILIS BENZOAS

Benzyl benzoate ȕĬȒǿǥǤĚ Ɩ ƐǋȒǿǥǤ

$C_{14}H_{12}O_2$:**Molecular formula** ĞĒİĄÂƨǟ ĞȣĒÔǚǟ

212.3 :**Relative molecular mas** ĞĒǤÊĄǚǟ ĞĒİĄÂƨǟ ĞŸǪÒǚǟ

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Phenylmethyl benzoate; CAS Reg. No. 120-51-4.

.[illegible] :**Description** [illegible]

[illegible] TS ([illegible] 750 ~) [illegible] :**Miscibility** [illegible]
.R [illegible]

.([illegible]) [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]
.[illegible]

.[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]
.$C_{14}H_{12}O_2$ [illegible] %100.5

:**Identity tests** [illegible]

[illegible] 10 [illegible] TS2 [illegible] 25 [illegible] 2 [illegible]
:[illegible] 15 [illegible]
[illegible] 5 [illegible] 1 [illegible] :A
[illegible] VS ([illegible] 0.02) [illegible] 1 [illegible] TS ([illegible] 50) [illegible]
.[illegible]

[illegible] TS ([illegible] 100~) [illegible] 10 [illegible] :B
.([illegible]) °[illegible] 123 [illegible]

.°[illegible] 17.0 [illegible] :**Congealing temperature** [illegible]

$n_D^{20} = 1.658 - 1.570$:**Refractive index** [illegible]

.ρ_{20} = 1.116 - 1.120 g/ml :**Mass density** [illegible]

ȯǫᵩǍǯǚǗ Ȏᶇ 15 Ž ȟ 0.30 ǟǡǾǂ ǿǍǤǬǹ ᵲǟ ȯǫǙȚ ƘȒƠ ǤǮ8ǣ ¦**Chlorinated compounds** ǥǿǭǙȮǭǟ ğǍǤǤȭǛǠǟ
ʔǙȝ ȨǝǍǭǻ 5 ǥǽᶇ ȯǫǙǂǟ ǖǫǽǂ .TS (ȯ/ȟ 80~) ÿǫǻǫȎǟǟ ǼǮȆȭşǿǼǮȽ ȯǫǙȚ ȡᶇ Ȏᶇ 6 ȣǍȒǍş TS (ȯ/ȟ 750 ~)
ȯǫǙǂǟ ȎǅǰȘ .TS (ȯ/ȟ 130~) ȭǍǍǬǍǟǟ Ȑᵽ ȡᶇ Ȏᶇ 3 ȣǍȒǍş ǕǦᵩǿǍȎᶇ ǟǫǤǚ Ƃǚ ȎǬǍǂş ǕǻǍǍǂ .ɄǝǍᶇ ÿǍᵽ
Ƃǚ TS (ȯ/ȟ 130) ȭǍǍǬǍǟǟ Ȑᵽ ȡᶇ Ȏᶇ 4ş ClTS ȭǍǿǫǙȭşǿǼǮȚǟ Ȑᵽ ȡᶇ Ȏᶇ 2.0 ǷȎǍǍᶇ ȎǬǍǂ ɄǨǅǍȶǟ
(ȯ/ȟ 40) ǤȒǍǟǟ ğǟǍǬᵩ ȯǫǙȚ ȡᶇ Ȏᶇ 0.5 ƙǣǫǤᵩȘǟ ȡᶇ Ȏȭ Ƃǚ ȣǍȒǍ .Ȏᶇ 25 Ƃǚ ǒǍȶǍǣ ƷǍǺǂş ǕǦᵩǿǍȎᶇ ǟǫǤǚ
ɉǫȮǩ ᵲ .ǍǐǍǤȶǟ ȄȽȊǟǟ ǒǫȓ ȡᶇ ǤǮȽȚ ǕȨǝǍǭǻ 5 ǥǽᶇ ǞǦǍǅ ȝȓǫǩş ɄǅǍǅǟ ǼǮȒȩ ǤǕȅǟǫǣ ǈǍǵ ǯǍȽǂş .TS
.ǿǫǙȮǟǟ ȡᶇ ȟ/ᶇǙᶇ 0.33 ȡȝ ǼǍǍ ᵲ ǛɄǨǅǍȶǟ ȯǫǙǂǟ ȡᶇ ǤΘǍǍǟǟ ȭǙǩ ȡᶇ ʔǫȩǚ ǿǍǤǬǹ ᵲǟ ȎǻǍȅ ȡᶇ ǤΘǍǍǟǟ ÿǫȽ8ǟǟ

ȯǫǙɄᶇ ǍǍǍǂş ǕȯǼǮǭȆȶǟ TS ȯǫᵩǍǯǍզǟ ȡᶇ Ȏᶇ 5 Ƃǚ ǿǍǤǬǹ ᵲǟ ȎǝǍȅ ȡᶇ Ȏᶇ 5 ȣǍȒǍ ¦**Acidity** ǤȓǫȽΣǟ
ᵲ ǛǍǨȊȽȭ TS ȯǫᵩǍǯǍǚ/ƙǍǒǍǯǫ ȯǫǼǍǟǟ ȯǍȽǨǬȅǍǣ ǕVS (ȯ/ȯǫᶇ 0.1) ğǍᵩǫǣǍȮǟǟ ȡᶇ ƂǍʅǟ ÿǫǻǫȎǟǟ ǼǮȆȭşǿǼǮȽ
.(ɄǙǍᵩǍȩ) ǍǨȊȽǙǟ ʔǕȅǫǟǟ ǤǕȎǍǟǟ ɉǫǒ ʔǙȝ ȯǫȎΣǟ ȎǅȘ 0.3 ȡᶇ ǍǯȭǗ ǼǮǕǬǍ

ȯǫᵩǍǯǍǚ/ÿǫǮȅǍǩǫǤǟǟ ǼǮȆȭşǿǼǮȽ ȯǫǙȚ ȡᶇ Ȏᶇ 40 Ƃǚ ǕǤǮǖǫǤȒᶇ ǤᵩşǟǍǫᶇ Ǖȟ 2.0 ǤǟǟǍȩ ȣǍȒǍ ¦**Assay** ǤȆǍǍȎȶǟ
ȭǍǿǫǙȭşǿǼǮȚǟ Ȑᵽ ȯǫǙɄᶇ ǍǍǍǂş ǕǻǮǂ .ǤȝǍȅ 1 ǥǽᶇ ɄȝǫǅǍǟǟ ɉǍǍǍƨǍǣ ƷǯȮᶇ ƘƠ ʔǙ8ǂş VS (ȯ/ȯǫᶇ 0.5)
ǻǟǍȶǟ ǿǍǤǬǹզǟ ȎǝǍȅ ɉşǻ ǤǮǙȽǨǟǟ ǻǍǨǂ .ǍǨȊȽȭ TS ȯǫᵩǍǯǍǚ/ƙǍǒǍǯǫ ȯǫǼǍǟǟ ȯǫǙȚ ȯǍȽǨǬȅǍǣ ǕVS (ȯ/ȯǫᶇ 0.5)
VS (ȯ/ȯǫᶇ 0.5) ȯǫᵩǍǯǍǚ/ÿǫǮȅǍǩǫǤǟǟ ǼǮȆȭşǿǼǮȽ ȯǫǙȚ ȡᶇ Ȏᶇ 1 Ȏȭ .ǤǍǿşǍȓ ğǍɄǮɄȎǩ ǤǬǚ ǾǍǺǂş ȼȎɄǫ
.$C_{14}H_{12}O_2$ ȡᶇ ᶇǙᶇ 106.1 ǘǫǍȮǍ

ØØØØØ

BENZYLPENICILLINUM KALICUM

Benzylpenicillin potassium !ǊǐƨƑǊǤǁ ǅǐǂƨǤ ǖǐȒǿǤ

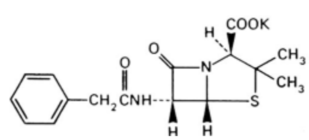
non - injectable enzylpenicillin potassium ǅǆΘǂ ǖǤƑǁ ƥǐȝ !ǊǐƨƑǊǤǁ ǅǐǂƨǤ ǖǐȒǿǤ

Benzylpenicillin potassium, sterile !ǐƽǁ Ǖ!ǊǐƨƑǊǤǁ ǅǐǂƨǤ ǖǐȒǿǤ

$C_{16}H_{17}KN_2O_4S$ ¦**Molecular formula** ǤǮǍǍƨǟ Ǥ8ǮȎǟǟ

372.5 ¦**Relative molecular mass** ǤǮȆǍǟǟ ǤǮǍǍƨǟ ǤǙǬȮǟǟ

¦**Graphic formula** ǤǮᵩǍǮǤȶǟ Ǥ8ǮȎǟǟ



:**Chemical name** [illegible]

Potassium (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate; potassium [2*S*-(2*α*,5*α*,6*β*)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylate; CAS Reg. No. 113-98-4.

.[illegible] :**Description** [illegible]

.R [illegible] R [illegible] :**Solubility** [illegible]

.[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]
.°[illegible] 25 [illegible]

[illegible] :**Labelling** [illegible]
.[illegible]

[illegible] :**Additional information** [illegible]
[illegible]
.[illegible]

REQUIREMENTS [illegible]

[illegible] %96.0 [illegible] :**General requiment** [illegible]
.[illegible] $C_{16}H_{17}KN_2O_4S$ [illegible] %102.0

:**Identity tests** [illegible]

.[illegible] C [illegible] B [illegible] C [illegible] A [illegible] •

[illegible] :A
[illegible] .(43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region
reference spectrum [illegible] RS [illegible]
.[illegible]

([illegible] 1760~) [illegible] 2 [illegible] 1 [illegible] 2 [illegible] :B
2 [illegible] 1 [illegible] TS
[illegible] TS [illegible] 2[illegible] 1 [illegible]

[illegible] 1 [illegible]

[illegible] (80~ [illegible]) TS [illegible] 2 [illegible] :C

"General identification tests [illegible] (123 [illegible] 1 [illegible]).

Specific optical reaction [illegible] 20 [illegible] $[\alpha]_D^{20°C}$ = +270 to +300°.

Clarity and colour of solution: [illegible] 0.20 [illegible] 10 [illegible].

Loss on drying [illegible] 105 [illegible] 10 [illegible].

pH value: [illegible] 20 [illegible] 5.0 - 7.5.

Light - absorbing impurities: [illegible] 1.9 [illegible] 280 [illegible] 350 [illegible] 0.10.

Assay: [illegible] 50 [illegible] 1000 [illegible].

[illegible] 2.0 [illegible] 10.0 [illegible] TS [illegible] 60 [illegible] 25 [illegible] 20 [illegible] (A [illegible]).

[illegible] 10.0 [illegible] (B [illegible]).

[illegible] 1 [illegible] 325 [illegible] 2.0 [illegible] 10.0 [illegible] TS [illegible] A [illegible] B.

[illegible] $C_{16}H_{17}KN_2O_4S$ [illegible] B [illegible] A [illegible] RS [illegible] 1 [illegible] RS ($C_{16}H_{17}N_2NaO_4S$) [illegible] 1.045 [illegible] ($C_{16}H_{17}KN_2O_4S$).

[illegible] 0.62 ± 0.03.

!ĭƨyⅡ !Njĭ ƨƑNjǦⅡ Dži ƨǅ üĭȐøǅ üШŬ hïǯƑȚ lƑǤƯĐž

Additional Requirements for Sterile Benzylpenicillin Potassium

Sterility testing of ǦⅠζƎΣä ğäáÂȒŁŸö ǦηÂÖĬöä øÂǤǫǹä" ȷäζÂȝ ǨƠ åøȿ Âţ ÆƎDzǫÊǩ ¦**Sterility** ǦηÂÖĬöä ȿÜ TS äÂÆŸÊǤöä ǦζÂȓÜ ȝƞ ŏÂÎ8öÂæ ǴƎĭÀǫöä øÂǤǫǹä ğäöäÀDZä ÂǹÜ ĘƎǤÛǫæ Û(162 ǦĦÂÔöä Û1 ÆŸŎä) "antibiotics .ÀĩÂǤţä øÂǤǫǹȓä ğäöäÀDZä

!ĭƨyⅡ üƑDžyƗƨúⅡ ƞyDžⅡ !Njĭ ƨƑNjǦⅡ Dži ƨǅ üĭȐøǅ üШŬ hïǯƑȚ lƑǤƯĐž

Additional requirements for Benzylpenicillin potassium for sterile use

Test for sterility of non - ȸÖĦŸö ǦŸæÂÖöä Ƙȡ ğäÂȒĦǫÊţä ǦηÂÖȝ ÖDZǰ øÂǤǫǹȓä" ȷäζÂȝ ǨƠ åøȿ Âţ ÆƎDzǫÊǩ .(ǦⅠÂƎŸƱqä ǦĬǤÛöä Ž 32 ǦĦÂÔöä Û5 ÆŸŎä ÀȚǫä) "preparations injectable

øÂǤǫǹȓä" ȷäζÂȝ ǨƠ 8ζòζƞ ζŁ ÂŁõ øÂǤǫǹȓä ĘƎÛƗ ¦**Bacterial endotoxins** ǦƎƞζǫÀƨä ǦƎŸǹäÆöä ğÂφÂⅠØöä ȓ Ü(ǦⅠÂƎŸƱqä ǦĬǤÛöä Ž 30 ǦĦÂÔöä Û5 ÆŸŎä) "Test for bacterial endotoxins ǦƎƞζǫÀƨä ǦƎŸǹäÆöä ğÂφÂⅠØöä ÖDZǰ .ƙŸÊǤöä ÖⅠÂøÂæ ȸƞ ƞŸƞ 1 Öõ Ž RS ɄŸǹäÆöä ȷÂⅠØöä ȸƞ ǦƎöȿå ǥÆǵȿ 0.01 ȸƞ ÀǰõÜ Ƀζȝ

ØØØØØ

BENZYLPENICILLINUM NATRICUM

Benzylpenicillin sodium !NjĭƞNjȚⅡ Dži ƨǅ üĭȐøǅ

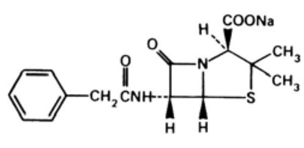
Benzylpenicillin sodium (non - injectable) (ȸÖĦŸö ÖæÂÖöä Ƙȡ) ȳζåζÔöä ƙŸÊÂæ ÖⅠÂøÂæ

Benzylpenicillin sodium, sterile !ĭƨyⅡ Û!NjĭƞNjȚⅡ Dži ƨǅ üĭȐøǅ

$C_{16}H_{17}N_2NaO_4S$ ¦**Molecular formula** ǦƎÂⅠÂƨä Ǧ8ƎÔöä

356.4 ¦**Relative molecular mass** ǦƎǤÊÂöä ǦƎÂⅠÂƨä ǦŸǫÒöä

¦**Graphic formula** ǦƎφÂƎǤţä Ǧ8ƎÔöä



¦**Chemical name** ɄǝÂƎŁƎÒöä ȴèȓä

Sodium (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate; sodium [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0]-heptane-2-carboxylate; CAS Reg. No. 69-57-8.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] 0.5 [illegible] R [illegible] R.

[illegible] **Category**: [illegible].

[illegible] **Storage**: [illegible] 25 °[illegible].

[illegible] **Labelling**: [illegible].

[illegible] **Additional information**: [illegible].

[illegible] **General requirement**: [illegible] 96.0% [illegible] 102.0% [illegible] $C_{16}H_{17}N_2NaO_4S$ [illegible].

[illegible] **Identity tests**:

- [illegible] A [illegible] B [illegible].

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 2 [illegible] 1 [illegible] 2 [illegible] (1760~ [illegible]) [illegible] TS [illegible] TS [illegible] 2 [illegible] 1 [illegible] 2 [illegible].

C: [illegible] "General identification tests" ([illegible] 1 [illegible] 123) [illegible] B [illegible] (60~ [illegible]) TS.

20 [illegible] :**Specific optical rotation** [illegible] $[a]_D^{20\,°C}$ = +280 to +310°.

[illegible] 10 [illegible] 0.20 [illegible] :**Clarity and colour of solution** [illegible].

[illegible] :**Loss on drying** [illegible] 105 [illegible] 10 [illegible].

[illegible] 20 [illegible] :**pH value** [illegible] 5.0 - [illegible] 7.5.

[illegible] :**Light-absorping impurities** [illegible] 1.8 [illegible] 1 [illegible] 280 [illegible] 325 [illegible] 0.10 [illegible].

[illegible] :**Assay** [illegible] 50 [illegible] 1000 [illegible] 2.0 [illegible] 10.0 [illegible] TS [illegible] 60 [illegible] 25 [illegible] 20 [illegible] (A [illegible]).

[illegible] 10.0 [illegible] (B [illegible]).

[illegible] 325 [illegible] 1 [illegible] 2.0 [illegible] 10.0 [illegible] TS [illegible] A [illegible] B [illegible].

[illegible] A [illegible] B [illegible] $C_{16}H_{17}N_2NaO_4S$ [illegible] RS [illegible] 0.62 ± 0.03 [illegible].

[illegible]

Additional Requirements for Sterile Benzylpenicillin Sodium

[illegible] :**Sterility** [illegible] Sterility testing of antibiotics" [illegible] (162 [illegible]) [illegible] TS [illegible].

!ĭšуΠε üƑDžуƗƨúΙΙ ƺуDžΙΙε !NjĭƣNjƬΙΙε DžĭƗƨæǴ üĭƦøæǴ üШǓ ƕĭʒƑƮă lƑǴƗƯƗDž

Additional requirements for Benzylpenicillin potassium for sterile use

Test for sterility of non - ȸŌĦŸō ǦŸæǺŌöä Ƙḑ ğäÂȒĦǫÊƫä ǦŋǺŌʒ ŌDZɟ øǺǦǹŕä" ɈäȥAʒ ƘƠ åøȘ Ăƫ ÆĒDzǫÊΛ

.(ǦΛÂĒŸƠqä ǦȞǦÛöä Ž 32 ǦĦȦÔöä Û5 ÆŸŎä) ȂȚöä) "in jectable preparations

øǺǦǹŕä" ɈäȥAʒ ƘƠ Ȣȥòȥŋ ȥĿ Ăŧõ øǺǦǹŕä ĘƭÛɫ :**Bacterial endotoxins** ǦĒŋȥǫȀƨä ǦĒŸǹäÆöä ğȦɸȦΛØöä

ɟ Ü(ǦΛÂĒŸƠŕä ǦȞǦÛöä Ž 30 ǦĦȦÔöä Û5 ÆŸŎä) "Test for bacterial endotoxins ǦĒŋȥǫȀƨä ǦĒŸǹäÆöä ğȦɸȦΛØöä ŌDZɟ

.ƙŸÊΛǦöä ŌΛÂøAæ ȸŋ ŊŸŋ 1 Ōõ Ž RS ɄŸǹäÆöä ɈȦΛØöä ȸŋ ǦĒöȘå ǥÆǵȘ 0.01 ȸŋ ȀǯõǗ Ƀȥʒ

øøøøø

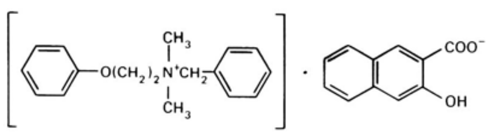
BEPHENII HYDROXYNAPHTHOAS

Bephenium hydroxynaphthoate !NjĭǿĭƻĭǴΙΙε lεNjƙʒƑǿ Ĭƨ lNjβƣĭlj

$C_{28}H_{29}NO_4$:**Molecular formula** ǦĒȦΛÂƨä Ǧ8ĒÔöä

443.5 :**Relative molecular mass** ǦĒǦÊΛöä ǦĒȦΛÂƨä ǦŸǪȮöä

:**Graphic formula** ǦĒɸȦĒǦƫä Ǧ8ĒÔöä



:**Chemical name** ɄəȦĒŧĒȮöä ȴèŕä

Benzyldimethyl(2-phenoxyethyl)ammonium 3-hydroxy-2-naphthoate (1:1); *N,N*-dimethyl-*N*-(2-phenoxyethyl)benzenemethanaminium salt with 3-hydroxy-2-naphthalenecarboxylic acid (1:1); CAS Reg. No. 3818-50-6.

ƇÆʒ ȘǗ ǦĦəäȀöä ƇÆʒ ÜȀȒǹɟä ƂǗ äøȦȓ ȀȦòǗ ƂǗ ȀȦòǗ ɈȥŸæ ɃøȥŸæ ȧȥĦÊŋ :**Description** ȤòȥöäГ

.ǶǦΛȀŌƙ ǦĦəäȀöä

äȁȘæ ÜR ȳøȥȥȘøȥŸȮöä Ž ɟȘ R ȸΛÂøǺǦöä Ž ɟȘ R Ƙǫɟä Ž ɟȘ ŏȦƫä Ž ǺĒŸŧʒ äȁȘæ Ƙḑ :**Solubility** ǦĒɸȦæȘØöä

.TS (ȯ/ȟ 750~) ȯȥɸȦǯΛqä ȯȥŸƮ ȸŋ ǺõÂDZ 50 Ž

.ɈäÆΛÆŸō åøȦù :**Category** ǦȦΛȀöä

.ȳȦÒǵüæ ǦŌŸ8ŋ ǦΛȘȦǵ Ž ȳȥĒΛÆΛǦöä ğäȥǯȥȦɸ ɄÊõȘøÆĒŁ ȘȦǵ Æƶ :**Storage** ȸΛÂÅǫöä

[illegible] **Additional information** [illegible]
[illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] %99.0 [illegible] %101.0 [illegible] $C_{28}H_{29}NO_4$ [illegible].

Identity tests [illegible]

• [illegible] A [illegible] B [illegible] C [illegible].

A: [illegible] "Spectrophotometry in the infrared region [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Related substances [illegible]" [illegible].

C: [illegible] B [illegible] 254 [illegible] C [illegible].

C: [illegible] 170 °[illegible] [illegible].

[illegible] **Chlorides** [illegible] 0.7 [illegible] 30 [illegible] 10 [illegible] (130~ [illegible]) TS [illegible] "Limit test for chlorides [illegible] (124 [illegible] 1 [illegible]) [illegible] 0.35 [illegible].

[illegible] **Sulfated ash** [illegible] 2.0 [illegible].

[illegible] **Loss on drying** [illegible] 105 °[illegible] 10 [illegible].

[illegible] **Related substances** [illegible] "Thim-layer chromatography [illegible] (84 [illegible] 1 [illegible]) [illegible] silica gel R4 [illegible] 5 [illegible] 4 [illegible] 1 [illegible] (300~ [illegible]) TS [illegible] 40 [illegible] (A) [illegible] R [illegible] 3 [illegible] 5 [illegible] 1 [illegible] 0. 40 [illegible] (B) [illegible] 1 [illegible] (C) [illegible] 1 [illegible] 0.40 [illegible] RS [illegible] 1 [illegible].

[illegible] (254 [illegible] 365 [illegible]). [illegible] 254 [illegible] A [illegible] B [illegible] C [illegible] 365 [illegible] A [illegible] B.

[illegible] Sodium molybdotungstophosphate TS [illegible] TS (200 [illegible]) [illegible] A [illegible] B [illegible] C. [illegible] A [illegible] R8 [illegible] B.

Assay [illegible] 0.4 [illegible] 30 [illegible] R1 [illegible] (0.1 [illegible]) VS [illegible] Non aqueous [illegible] titration [illegible] A [illegible] (142 [illegible] 1).

1 [illegible] (0.1 [illegible]) VS [illegible] 44.35 [illegible] $C_{28}H_{29}NO_4$.

ØØØØØ

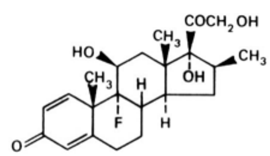
BETAMETHASONUM

Betamethasone [illegible]

$C_{22}H_{29}FO_5$:**Molecular formula** [illegible]

392.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione; CAS Reg. No. 378-44-9.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] (~750 [illegible]) TS [illegible]

[illegible] R.

[illegible] **Category**: [illegible]

[illegible] **Storage**: [illegible]

[illegible] REQUIREMENTS

[illegible] **General requirement**: [illegible] 96.0% [illegible] 104.0% [illegible] $C_{22}H_{29}FO_5$ [illegible]

[illegible] **Identity tests**:

• [illegible] A [illegible] B [illegible] C [illegible] D [illegible]

A: [illegible] "Spectrophotometry in the infrared region" (43 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible] R [illegible]

B: [illegible] 20 [illegible] 20 [illegible] (~750 g/l) TS [illegible] 2 [illegible] 20 [illegible] 2 [illegible] 10 [illegible] TS [illegible] 60 [illegible] 20 [illegible] 450 [illegible] 0.30 [illegible] 1 [illegible] 2 [illegible] 1 [illegible]

C: [illegible] "Related steroids [illegible]" [illegible] A [illegible] B [illegible] A [illegible] B.

D: [illegible] "Oxygen flask method [illegible]" [illegible] (132 [illegible] 7 [illegible] 0.5 [illegible] 0.01) [illegible] 0.1 [illegible] 0.1 [illegible] 20 VS (0.01 [illegible]) [illegible] 0.1 TS (1 g/l) Sodium alizarin sulfonate [illegible] TS [illegible]

[illegible] **Specific optical rotation**: [illegible] 5.0 [illegible] R [illegible]

$[a]_D^{20\,°C} = +114 \text{ to } +122°$.

Sulfated ash: 0.1 … 5.0 …

Loss on drying: 100 °C … 0.6 … 5 … 5.0 …

Related steroids: … silica gel R1 … (84 …) "Thim-layer chromatography" … 12 … R … 8 … R … 15 … R … 77 … 9 … 1 …

(B) … 1 … 15 … (A) … R … 1 … R … 2 … 1 … RS … 15 … 0.15 … (D) … 1 … BS A … (C) … BS A … 1 …

… blue tetrazolium … 10 … 105 … TS … D …

Assay:

• …

TS (… 750~) … 20 … 20 … 100 … 25 … 10.0 … 100 … TS (… 750~) … TS … blue tetrazolium … 2.0 … 2.0 … R … R … TS … tetramethylammonium hydroxide … 1 … R … TS (… 750~) … 30 … 525 … 1 … 25 …

TS (ȯ/ ȟ 750~) ǼǼŁǼõɟā ȸņ ƂǺƪā ȯƺǷǺǮɋā ȯƺŸȚ ȸņ Ǒņ 10 ǴƨǺȞņ ǺȒĦǂŀ ȯƺŸȚ ɁŸȝ ɃƺǪƠ ǼǺǾņ ǥǨDzǵ
ȼǽÂ Î ǪõǺǽ î ƺǂǺƫā ÛRS ɉȘǟǺǮƐņǺǪƐǴõā Ȝņ ǴǬǿǺǑƫǺǽ ǴòƺǂǺƫā ǥǻǺƫā Ž C₂₂H₂₉FO₅ ǿāǼǑņ ǼÊǂŀ .ȼǽÂ Î ņ ǟƺŸèüǽ
.ȸņāÂǪõāş

ØØØØØ

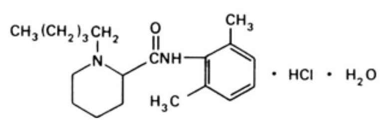
BUPIVACAINI HYDROCHLORIDUM

Bupivacaine hydrochloride ǅĩĩƑǀƑƧĭǴǈǴǁƐ ǫĭƥǈǂǀǈƥǫĭǉ

$C_{18}H_{28}N_{2O}$, HCl , H_2O ¦**Molecular formula** ǴƐǺǺÂƨā Ǵ8ƐÔõā

342.9 ¦**Relative molecular mass** ǴƐǴÊǺõā ǴƐǺǺÂƨā ǴŸǪȮõā

¦**Graphic formula** ǴƐǬǺƐǴƫā Ǵ8ƐÔõā



¦**Chemical name** ɄəǺƐȽƐȮõā ȴèɍā

1-Butyl-2′,6′-pipecoloxylidide monohydrochloride monohydrate; 1-butyl-*N*-(2,6-dimethylphenyl)-2-piperidinecarboxamide monohydrochloride monohydrate; CAS Reg. No. 73360-54-0.

.ǴĦəāÀõā ĆǼȜ ÜȒƐǽÜ ɉƺŸǽ ɃǿƺǼǽ ȧƺǂÊņ ¦**Description** Ȥòƺõā

ɉǺǽşǾõā ǴƐǂì ÜTS (ȯ/ ȟ 750~) ȯƺǷǺǮɋā ȸņ ŏāÂDZÜ 8 Žş ŏǺƫā ȸņ ǼõÂDZ 25 Ž ǟǽşǽ ¦**Solubility** ǴƐǬǺǽşǾõā
.R ȳǿƺƺşǿƺŸȮõāş R ƙǪɟā Ž

.ɄĤȑƺņ ȷǺǽ ¦**Category** ǴǺǺõā

.ǼǼƐDZ ǴǑŸ8ņ ǴǺşǺǵ Ž ƙǺǺõǺǺǼǽƺǴõā ǼǺǿƺŸõşǿǼǼŁ ȘǺǵ Ǽƶ ¦**Storage** ȸǺÂǺǺǪõā

REQUIREMENTS ƘǴǂǁƱƙdž!ƒ

ǼǺÂǺ ɍş %98.5 ȸȝ ǑǑǺ ɍ Ǻņ ɁŸȝ ƙǺǺõǺǺǼǽƺǴõā ǼǺǿƺŸõşǿǼǼŁ ɃƺǪȜ ¦**General requirement** ȳǺǨõā ǼŸÛǪƫā
.ǴǺǺǑõā ǥǻǺƫā ƂÜ ƫƺDZǺǺõǺǽ Ǵǽƺ ÊȚ Û$C_{18}H_{28}N_2O$, HCl ȸņ %101.0 ȸȝ

¦**Identity tests** ȟĭǈǈǉƐ ǀƐƥƑǴǂƢƐ

ŏǺǺȽ Σā ƘƠ ǴȞìɟā ǴǑÛǺņ Ž ɄəƺȒõā ȤƐÛõā ȃǺǽ" ɉāƺǺȝ ƘƠ 8ƺòƺņ ƺŁ ǺȽõ ÒǂǺõā ĘǼÛŀ :A

.(43 ǴĦɄȦÔöä Û1 ǼŸÕä) "Spectrophotometry in the infrared region

ʒɳ şǗ RS ƙȦȂõȦȂǼǽʐǤöä ǼȂǿʐŸõşǿǼǼȽ ȸɳ ǰǪȂ ɃǾöä Ⱬ ǼÛöä ʒɳ öäȦȶΣä ǨƠ ǴȞì ɉä Ž î ȦÔǪɳɍä ȤǼù ĘǽȦÛǪ

.ƙȂȦõȦȂǼǽʐǤöä ǼȂǿʐŸõşǿǼǼT *reference spectrum* ɄȞǅȦʈä ȤǼÛöä

.TS (ȯ/ȟ 7) ȯʐǼʐşȦǪǼǭ ɄǭŸǭ ȯʐŸȚ ȸɳ Ōɳ 20 8ȦȒȂş ǒȦʈä ȸɳ Ōɳ 10 Ž ȟ 0.15 ǟäǾɫ :B

ǑÊ8ɫ ÜǿʐŸǤǪöä ȀȂȦĦǪö ȧǿşǼŸö ɄŸǹȦǼöä ǴÛÊöä ǰĦÊɫ ȳşȂŸöä Ǽȝʒş ǻäǼǼö ǭȂȦǪȂ ÛɉȦǼŸ8öä ʔøǪǵ ǰȂȦʈä ȸȦǼÊɫ

ÜǥȂɳ Ōõ Ž Ōɳ 2 ȯȦȶȞǪèȦǽ ÛR ƘǭɉȦş R ȯʐǬȦǮǼʈä ȸɳ ǴǼöȂǪɳ ǧȦǼȶÒǽ Ǵʒʐ ǤǪɳ ÛöȦʈä ȸɳ ǥƘ8ò ǴǼȶÒǽ ǴʒȂÊǽ ǴǽȦèȂöä

.(ƙȂȦõȦȂǼǽʐǤöä ǧäȦÒǼǽ) °ȳ 194 ǴǽäȦę ǿȦȚÔǭɍä ǴǅʐǿǼǻ

General ǴɳȦȞöä 8äȦȞǪèɍä ǧäǿȦǤǪǹä" ɉäʐȝʒ ǨƠ 8ʐòʐʈä ÛB ŌʒȦȂǪöä Ōɳ/ɳŸɳ 2 ȂǼõȂǪǽ ȯʐŸɫä ɄÛȞȂ :C

.(121 ǴĦɄȦÔöä Û1 ǼŸǑä) ǧäǼȂǿʐŸȮŸö ȂǼȶɦ ŌʒȦȂǪõ "identification tests

ǴǼǝȦȂǭ ǧȦǪȂǼȂǗ ȯʐŸȚ ȸɳ Ōɳ 0.25 ǒȦʈä ȸɳ Ōɳ 10 Ž ȟ 0.25 ȂǼõȂǪǽ ȯʐŸȚ ƃǗ 8ȦȒȂ ׃**Copper** ǡȦĦȂöä

ǡȦĦȂöä ȸɳ ƃȦʅä ŌȂȂǪǼÊöä Ȁƥȸɳȟ 0.2 8ȦȒȂ ÜǴŌǼęǻ 2 ǥǼɳ ǿǿäȂŌǪèŸö ŌȂǪɫş ÛVS (ȯ/ȯʐɳ 0.05) ȳʐȂǻʐÔöä

sodium ȳʐȂǻʐÔöä ǧȦɳȦǽǿȦõʐǼǭ ɄǝȦȂǭ ŌǼǯȂä ɄǝȦȂǭ ȯʐŸȚ ȸɳ Ōɳ 1ş TS (ȯ/ȟ 100~) ȦǼǭʐɳɉä ȯʐŸȚ ȸɳ Ōɳ 1ş ÛR

.ǴŌǼęǻ 2 ǥǼɳ R ɈʐǽȦÒöä ǼȂǿʐŸõ Ʉʒȁǿ ȸɳ Ōɳ 10 ǴÛèäʐǽ ȮǬȂǺǪÊɫş TS (ȯ/ȟ 0.8) diethyldithiocarbamate

ȯʐŸȚ ȸɳ ȳʐǅʐǵ 3 ȸɳ ǰȂȦɳ ȸɳ Ōɳ 10 ǴǒȦȊʈǽ žȦȞȂ ȦɳǼȝʒ ǴΘȂȂöä ǴòŸʅä Ɉʐö ȸɳ Ęȶȡǚ ǴòŸʅä Ɉʐö ɈʐȮȂ ɍ

.ǒȦʈä ȸɳ ȦȶǅʐǴ 397ş TS (ȯ/ȟ 80) (II) ǡȦĦȂöä ǧȦȂŸè

Ōɳ 5 Ž ǴöȦȶǯöä ǟäǾɫş ǻȦǼɫ ÜFeR ǴǼǝȦɳŸöä ȳʐȂǻʐÔöä ǧȦǭʐǽȂõ ȸɳ ȟ 1 ʒɳ ȟ 1.0 (ȧȂĦɫ) ǼɳȂɫ ׃**Iron** ǼȂǼΣä

ɉäʐȝʒ ǨƠ 8ʐòʐɳ ʐȽ Ȧȶõ ȯʐŸɫä žȦȞɫ .ǒȦʈä ȸɳ Ōɳ 30ş FeTS (ȯ/ȟ 250~) ŌȂǿʐŸõşǿǼǼTä Ȁƥ ȸɳ

ǼȂǼΣä ȯʐŸȚ ȸɳ Ōɳ 0.5 ȯȦȶȞǪèȦǽ Û(129 ǴĦɄȦÔöä Û1 ǼŸǑä) "Limit test for iron ǼȂǼΣä ŌǅɉɃǼΣä ǿȦǤǪǹɍä"

.ȟ/ȳäȂȡşȂŌɳ 10 ȸʒ ǼȂǼΣä ʔʐǪȚ ǼȂÂȂ ɍ ÜFeTS ɃǿǼȞʈä

.ȟ/ɳŸɳ 1.0 ȸʒ ǼȂÂȂ ɍ ׃**Sulfated ash** ǨȦŸÊʈä ǻȦɳȂöä

45 ȸɳ ŌęǗ ǼŌȂȂ ɍ Ü°ȳ 105 ǥǿäȂǵ ǴǅʐǿǼǽ ǨǽȦǯöä ɈäʐȂöä ʔøǪǵ ȤȦƶ ׃**Loss on drying** ȤǼȂǅǪöȦǽ ǼŌȂöä

.ȟ/ɳŸɳ 60 ȸɳ ȂǯõǗ ɍş ȟ/ɳŸɳ

.6.0 - 4.5 ÛŌɳ/ɳŸɳ 10 ȂǼõȂǪǽ ȯʐŸȚ pH ǒȦȽȦǽ ɳŸǤ ׃**pH value** ǒȦȽȂǤöä Ǵȶǽę

ȤǼù (ȂǮȚɫ) ɃǼǤɫ ׃**Absorption in the ultraviolet region** ǴǼǅÊȂǤöä ȧʐʐ ǴȞì ɉä ǴŌÛȂɳ Ž î ȦÔǪɳɍä

ǯäʐɳɉä ȯäʐùǗ Ž ǼȽȦȊɫ ȦɳǼȝʒ ÛVS (ȯ/ȯʐɳ 0.01) ŌȂǿʐŸõşǿǼǼTä Ȁƥ Ž Ōɳ/ɳŸɳ 0.4 ȂǼõȂǪǽ ȯʐŸɫ î ȦÔǪɳɍä

ȯŸǹ ȸɳ î ȦȶǪöä ɈǗş .ȂǪɳʐǬȦǭ 271ş ȂǪɳʐǬȦǭ 263 ǴǽäȦę ǼȝʒƙǼȶȚʒǗ ƙòȂÔǪɳä ÛȂǪɳʐǬȦǭ 350ş ȂǪɳʐǬȦǭ 230 ƙǽ Ȧɳ

ǴǅʐʈäȯʐùǼȝʒşÛ0.58 ȸʒ ǼȂÂȂ ɍş 0.53 ȸʒ ŌŌȂ ɍ ȂǪɳʐǬȦǭ 263 ɄȶȚʒɉä ǴǅʐʈäȯʐùǼȝʒ ȴè 1 ǴǬȦǺǯǽ ǴŌǤù

[illegible] 2 [illegible] 0.48 [illegible] 0.43 [illegible] 271 [illegible]
[illegible] 1 [illegible].

[illegible] **Related substances**: [illegible] silica gel R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] R [illegible] 2 [illegible] TS (750~ [illegible]) [illegible] 1 [illegible] 0.50 [illegible] (B): [illegible] 1 [illegible] 50 [illegible] (A): [illegible] potassium iodobismuthate TS2 [illegible] A [illegible] B [illegible].

Assay: [illegible] 0.65 [illegible] 30 [illegible] R1 [illegible] TS [illegible] 10 [illegible] (0.1 [illegible]) VS [illegible] "Non-aqueous titration [illegible] A (142 [illegible] 1 [illegible]).
[illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 32.49 [illegible] $C_{18}H_{28}N_2O$, HCl.

[illegible]
Additional requirements for Bupivacaine hydrochloride for parenteral use
[illegible] "Parenteral preparations [illegible] 4 [illegible] 56 [illegible]).

Bacterial endotoxins: [illegible] "Test for bacterial endotoxins [illegible] 5 [illegible] 30 [illegible] 2.5 [illegible] RS [illegible] 1 [illegible].

ØØØØØ

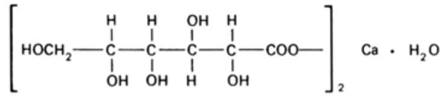
CALCII GLUCONAS

Calcium gluconate [illegible]

Molecular formula [illegible]: $(C_6H_{11}O_7)_2Ca$, H_2O

Relative molecular mass [illegible]: 448.4

Graphic formula [illegible]:



Chemical name [illegible]:

Calcium D-gluconate (1:2) monohydrate; CAS Reg. No. 299-28-5.

Description [illegible].

Solubility [illegible] R [illegible].

Category [illegible].

Storage [illegible].

Additional information [illegible].

REQUIREMENTS [illegible]

General requirement [illegible] %98.0 [illegible] %102.0 [illegible] $(C_6H_{11}O_7)_2Ca, H_2O$ [illegible].

Identity tests [illegible]:

A: [illegible] 20 [illegible] General [illegible] "identification tests [illegible] (120 [illegible]).

B: [illegible] 1 [illegible] 30 [illegible] 1 [illegible] (25 [illegible]) TS [illegible].

C: [illegible] 5 [illegible] 0.1 [illegible] 0.7 [illegible] R [illegible] 1 [illegible] R [illegible] 30 [illegible] 10 [illegible] Charcoal R [illegible] 200 [illegible].

Heavy metals [illegible] 1.0 [illegible]

Û1 ÆŸÕ ̈) 3 ǒäÀDZɋ ̈ ÆÊɰ Û"Limit test for heavy metals ǦŸĿŐǯöä (ğäÀŸÀöä) ȷåÅȞʦ ̈ ŌDZɉ ɃÆΣä øÀǤṅɍ ̈" ȷäζÀʒ .ȟ/ÿäÀʠȘÀÒɳ 20 ȸʒ ÆÂÀ ɍ Ü(128 ǦĦÀÔöä Û1 ÆŸÕ ̈) A ǦŐÀÛŸö ÅŐζȘ ǦŸĿŐǯöä ȷåÅȞʦ ̈ ʔζǬʈ ȸȞȞȽ Ü(127 ǦĦÀÔöä

ȸɳ Ōɳ 2 ȸɳ ȷÀɳ Ž ȟ 0.50 ā äØȽ :**Chlorides and other halides** ʔÀṅɉ ̈ ğäÆĿÀTäȘ ğäÆøζŸÒöä øÀǤṅɍ ̈" ȷäζÀʒ ǨƠ ȣζòζɳ ζȽ Àȶõ ŌȶȞöä ʔÀDzȽȘ ÛöÀʦ ̈ ȸɳ Ōɳ 20Ș TS (ȯ/ȟ 130~) ŌÀÀǤÂöä Ȓ ƥ ȯζŸʈ 0.5 ȸʒ ğäÆøζŸÒöä ʔζǬʈ ÆÂÀ ɍ Ü(124 ǦĦÀÔöä Û1ÆŸÕ ̈) "Limit test for chlorides ğäÆøζŸÒöä ŌDZɉ ɃÆΣä .ȟ/ɳŸɳ

ȸɳ Ōɳ 100 Ž ȟ 1.0 ā äØȽ :**Magnesium and alkaline metals** ǦÀζŸŌöä (ğäÂŸÀöä) ȷåÅȞʦäȘ ÿζÀÂøÀȣʦ ̈ (ȯ/ȟ 260~) ÅĿǬζɳɉ ̈ ȯζŸʈ ȸɳ Ōɳ 1Ș ÛTS (ȯ/ȟ 100) ÿζĿǬζɳɉ ̈ Æøζ Ÿõ ȯζŸʈ ȸɳ Ōɳ 10 ȣÀȒÀȘ ÛƂÀȣöä ǒÀʦ ̈ 4 ǥÆɳ øäÀŌǬèŸö õÀǬȽ .TS (ȯ/ȟ 25) ȸṅÀÊöä ÿζĿǬζɳɉ ̈ ğɍÀÊõÀ ȯζŸʈ ȸɳ Ōɳ 50 ÛǥÀÛŌöä ζŸǩ ǥÀÛçȘ TS ȷàȘ ÆÂÀ ɍ ÜÆɳÀȽȘ ȣÀÀƨ ̈ ɁøǬǵ ǦǵÀïÀöä ȸɳ 100 ÀÁȽ .ǴïÀȘ ÛǒÀʦÀ Ōɳ 200 ȴDZǵ ƃÜ ȤåÁȽ ÛğÀʒÀè .ɳŸɳ 2.0 ȸʒ ǦöÀȶǯöä

ζȽ Àȶõ ǦǵÀïÀöä ʒɳ ŌȶȞöä ŌȶÒǬÊÀ .ǴïÀȘ åÀÀȽ ÛƂÀȣöä ǒÀʦ ̈ ȸɳ Ōɳ 40 Ž ȟ 5.0 ā äØȽ :**Slfates** ğÀÀŸÊöä ÆÂÀ ɍ Ü(125 ǦĦÀÔöä Û1 ÆŸÕ ̈) "Limit test for sulfates ğÀÀŸÊöä ŌDZɉ ɃÆΣä øÀǤṅɍ ̈" ȷäζÀʒ ǨƠ ȣζòζɳ .ȟ/ɳŸɳ 0.1 ȸʒ ğÀÀŸÊöä ʔζǬʈ

ȸɳ Ōɳ 2 ȣÀȒÀȘ ÛȸṅÀÊöä ǒÀʦ ̈ ȸɳ Ōɳ 10 Ž ȟ 0.5 ā äØȽ :**Glucose and sucrose** àȘÀÒÊöäȘ àζõζŸȣöä ÿζÀåζÔöä ğÀǬζàÀõ ȯζŸʈ ȸɳ Ōɳ 15 ȣÀȒÀȘ ÛåƎÀ .ǦŌĿçå 2 ǦäÀç ɁŸȣÀȘ ÛTS (ȯ/ȟ 70~) ŌÀøζŸõȘøÆĿTä Ȓ ƥ ȯζŸʈ ȸɳ Ōɳ 2 ǦäÀç ƃÜ ǦĿζÀÔöä ǦǵÀïÀöä ȸɳ Ōɳ 5 ȣÀȒȽ .ǴïÀȽȘ ȨəÀçå 5 ǥÆɳ øäÀŌǬèŸö õÀǬȽ Ü(ȯ/ȟ 50) .ǦäÀèø ǦɳÜ ɍȘ ÀƥÜ ÀÒʒ ȷǬÀ ɍ ÜǦŌĿçå 1 ǥÆɳ ɁŸȣȽȘ potassio-cupric tartrate TS ÿζĿèÀǩζǦöäȘ ŌÀƎǬöä ğäÀüÀü

ÅĿζÀò ǒÀʦ ̈ ȸɳ Ōɳ 10 Ž ȟ 0.50 ÀĿõÀǬä ȯζŸɉ ̈ ȷζÒÀ :**Clarity and colour of solution** ȯζŸɉ ̈ ȷζöȘ ǒÀÀò Colour of ŌəäζÊöä ȷζö" ȷäζÀʒ ǨƠ ȣζòζɳ ζȽ Àȶõ ǦǬøÀŌʦ ̈ ÆÀʒ Yw1 ɃøÀĿȞʦ ̈ ȷζŸöä ȯζŸʈ ȸɳ ÅǬζŸǩ ÆĦïÜ ÈĿöȘ .(53 ǦĦÀÔöä Û1 ÆŸÕ ̈) "liquids

ȣζòζɳ ζȽ Àȶõ ǥÀÀȞʦ ̈ ʔÀDzȽ .ǒÀʦ ̈ ȸɳ Ōɳ 20 Ž ÛǦĿüζǦȒɳ ǦǬȘàζɳ ȟ 0.5 ǦäÀç ā äØȽ :**Assay** ǦÊÀŌʦ ̈ .(138 ǦĦÀÔöä Û1 ÆŸÕ ̈) ÿζĿÊöÀÒöä ŌDZɉ "Complexometric titrations ğäÆŌȞʦ ̈ ɑÀĿŌɳ ğäÀÀȞʦ ̈" ȷäζÀʒ ǨƠ .($(C_6H_{11}O_7)_2Ca$, H_2O ȸɳ ɳŸɳ 22.42 ȕζÀÒÀ VS (ȯ/ȯζɳ 0.05) ÿζÀåζÔöä ǦĿəÀǬ ğÀǬÀÆÀÜ ȯζŸʈ ȸɳ Ōɳ 1 Ōõ

Additional requirement for Calcium gluconate for parenteral use

.(36 ǦHȴȦÔöä Û4ÆŸÕä ȦŢφä) "Parenteral preparations ǦÆȦȬΣä ğäȦȒHȹÊţä" gåşȦzǘ Ž åøş Ȧţ ÆÆDzÊȦ øȦǤȹǹꞧä" ȷäzȦɜ ǨƠ 8zòzȠ zȽ Ȧȶõ øȦǤȹǹꞧä ĘǤÛȦ :**Bacterial endotoxins** ǦÆȠzȹȦƨä ǦÆŸǹäÆöä ğȦφȦȦØöä ꞧ Ü(ǦȦÂÆŸƱqä ǦȞǤÛöä Ž 30 ǦHȴȦÔöä Û5 ÆŸÕä) "Test for bacterial endotoxins ǦÆȠzȹȦƨä ǦÆŸǹäÆöä ğȦφȦȦØöä ŌDzɉ .ȟ 1 Ōõ Ž RS ɄŸǹäÆöä ȷȦȦØöä ȡȠ ǦÆöşå gÆǵş 167 ȡȠ Ȧǯȭü ɃzƷ

ØØØØØ

CARBO ACTIVATUS

Charcoal , activated üŷƻDŽǁƐ ƯǗȠ ǆDŽǁƐ Û!ƟƻǁƐ

.ǦHȴäȦöä ƇÆɜ ǗǦφz Î ʅä ȡȠ ṗȦǹ ÛȴɜȦφ Ûåzèü ȷzŸä ȧzHȴÊȠ :**Description** Ȥòzöä

.ǦȦåȦÆȹɜꞧä ğȦǤȦØţä ɜÆƤ Ž ꞧş öȦţä Ž ȦÆŸȶɜ āȦşæ Ƙȡ :**Solubility** ǦÆφȦæşØöä

.ǦÆφꞧÆÆò ǦÆÆĦȠ ǗǦȠȦɜ ǦȦȡ şæ ȧȦȦøå̋ :**Category** ǦȦȦöä

.ȦÆÆDZ ǦŌŸ8ȠǦȦşȦǵ Ž (ŌȞȦţä) ǛǹÎȦţä ȴHȴȦöä ȘȦǵ Ǣʑ :**Storage** ȡȦÂÅȹöä

.ȧäØţä ƇÆɜ ȧzHȴÊȠ (ŌȞȦţä) ǛǹÎȦţä ȴHȴȦöä :**Additional information** ǦÆzȦȑ ü ğȦȠzŸȞȠ

REQUIREMENTS ƘǦȴǁƱƙǆž!ƒ

ȷşÆæ öɄÛæ ŌȮÎæ ȧȦȹɜ ǛøäȦþꞧä ɁØȹǵ øȦǤȹǹꞧä gåȦȠ ȡȠ gƘ8ò ǦÆȶõ ȡȦÅÊȴ :**Identity test** ǦȦzŢä øȦǤȹǹä .ÆT

70~) ŌȦøzŸõşøÆÆTä Ȓþ ȡȠ ŌȠ 20 ȡȠ ǰȦÂȠ ɜȠ ȟ 1 ɁŸ8ȴ :**Heavy metals** ǦŸÆȬǯöä (ğäÂŸȦöä) ȷåȦȞţä ğȦǵȦïȦöä ȦȞȦȴ .ƃȦ8öä öȦţä ȡȠ ŌȠ 50 øäÆŌȠ ŌÊ8ȴş ÛǴǹȦȴ ÛĘəȦęå 5 gÆȠ TS1 ÿşƎöä òzŸŢ ȡȠ ŌȠ 5ş TS (ȯ/ȟ ŌȠ 20ş ÛVS (ȯ/òzȠ 1) ŌȦøzŸõşøÆÆTä Ȓþ ȡȠ ŌȠ 1 ǦȯȦȶǯöä ƃü 8ȦȒȦş ɄəȦȠ ÿȦþ ɁŸɜ 8ȦȦƨä ɁØȹǵ ǦƟȦȦöä ǴǹȦȴ ÛǨȦƎȮöä ÆÆÊõü ɄəȦȦφ åȦù ȴȹȦ ɁØȹǵ ȯzŸǂä ɁŸ8ȴ .TS (äzȹȦƎȮöä) äşøzȦŸÊöä Ȓþ ȡȠ ŌȠ 5ş ÛöȦţä ȡȠ (ğäÂŸȦöä) ȷåȦȞţä ɁzȹŢ ȡȞȞȴş øȦǤȹǹä òzŸHȶõ ŌȠ 50 ŌȶȞȹÊȦ .ŌȠ 50 ȴDzǵ ɁØȹǵ öȦţȦæ ȤȧÅȴş ÛgøşȦȒöä Æȹɜ Û"Limit test for heavy metals ǦŸÆȬǯöä (ğäÂŸȦöä) ȷåȦȞţä ŌDzɉ ɃÆΣä øȦǤȹǹꞧä" ȷäzȦɜ ǨƠ 8zòzȠ zȽ Ȧȶõ ǦŸÆȬǯöä .ȟ/ÿäȦȡşȦȮȠ 100 ȡɜ ÆȦÂȦ ꞧ Ü(128 ǦHȴȦÔöä Û1 ÆŸÕä) A ǦŌȦȦÛŸö ȦŌzş

.R ŌȦȦùȦÛöä Ȓþ ȡȠ ȟ 2ş öȦţä ȡȠ ŌȠ 50 ɜȠ ȟ 5 ÛƘÛŌǩ äȦƬDZ Ž ÛǦȦȦȞæ ȡȦÅÊȴ :**Cyanides** ğäÆÆφȦÆÊöä (ȯ/òzȠ 1) ÿzȦåzÔöä ÆÆÊõşøÆÆȽ òzŸŢ ȡȠ ŌȠ 2ş öȦţä ȡȠ ŌȠ 10 ȡȠ ǰȦÂȠ Ž gøȦÛŌöä ȡȠ ŌȠ 25 ǦæäȦę ɜȶDzȴ

[illegible] 0.05 [illegible] 25 [illegible] 50 [illegible] VS

250~) [illegible] 10 [illegible] 70 [illegible]

[illegible] TS (ö/ȟ

[illegible] 5 [illegible] 20 [illegible] 1 [illegible] **Sulfides** [illegible]

[illegible] TS (ö/ȟ 250~) [illegible]

.TS (ö/ȟ 80~)

[illegible] TS (ö/ȟ 130~) [illegible] 25 [illegible] 1 [illegible] **Zinc** [illegible]

[illegible] 10 [illegible] 5 [illegible]

:(B) [illegible] dithizone method (A) [illegible]

[illegible] 3.0 [illegible] 3.0 [illegible] 10 [illegible] :A

[illegible] 5.0 [illegible] TS [illegible] 5.0 [illegible] TS (ö/ȟ 60) [illegible]

3-2 [illegible] .R [illegible] R dithizone [illegible] 30 [illegible]

20) [illegible] 0.5 [illegible]

[illegible] 9.5 [illegible] TS [illegible]

.transmitted [illegible]

[illegible] :B

.(47 [illegible] 1 [illegible]) "Atomic absorption spectrophotometry [illegible]"

[illegible] 100 [illegible] 10 [illegible] **Fluorescent substances** [illegible]

[illegible] 365) [illegible] 100 [illegible]

0.005) [illegible] 1000 [illegible] quinine R [illegible] 0.083 [illegible]

.VS (ö/ö[illegible]

[illegible] **Ethanol-soluble substances** [illegible]

[illegible] 10 [illegible] .TS (ö/ȟ750~) [illegible] 50 [illegible] 2 [illegible]

.Yw1 [illegible] TS (ö/ȟ750~) [illegible] 50 [illegible]

.(ȟ/[illegible] 5) [illegible] 8 [illegible] 105 [illegible] 40 [illegible]

[illegible] 5 [illegible] 20 [illegible] 1 [illegible] **Acid-soluble substances** [illegible]

[illegible] 10 [illegible] 5 [illegible] TS (ö/ȟ 420~) [illegible]

TS (~1760) 1 ... 35

Alkali-soluble coloured matter: 0.25 ... 10 ... 10 ... 1 ... TS (~80) ... Gn2

Sulfated ash: 50

Loss on drying: 4 ... 120 ... 150

Acidity or alkalinity: 2 ... 40 ... 5 ... 20 ... R ... 10 ... 0.25 ... TS 0.25 ... VS (0.02)

Adsorbing power:

A: 1 ... 120 ... 4 ... 100 ... R ... 50 ... 5 ... 10 ... 10 ... 1 ... 5 ... TS (~420) ... potassio - mercuric iodide TS

B: 50 ... 100 ... methylthioninum chloride TS (1) ... 0.250 ... 5 ... 20 ... 250 ... 25 ... 50 ... TS (60) ... 35.0 ... VS (0.05) ... 50 ... 10 ... 10 ... 30 ... 3 ... VS (0.1) ... 100

VS (ȯ/ȯɀɳ 0.05) ǻɀǼöä ȯɀŸʈ ȡɳ ğäÀǪö ƟŸŧä ǻÆȝ ÆÊȜ .ǥÀÁǨŧä ǦÁŒ ȡɳ āäÀǪɛɍä ÆÁȝ TS ÀÎÁöä ȯɀŸʈ
.Ōɳ 0.7 ȡȝ ƙȶǲΣä ƙæ ȧÀÁöä ŌŌÁ ɍ ǕǥÀÁǨɳ ŌÕ Ž ǦǬǇȚǪÊŧä

ØØØØØ

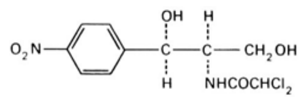
CHLORAMPHENICOLUM

Chloramphenicol üǋǀǏǈǅŽƥǋǂǀ

$C_{11}H_{12}C_{l2}N_2O_5$ ¦**Molecular formula** ǦǼÀÂɾä Ǧ8ǼÔöä

323.1 ¦**Relative molecular mass** ǦǼǴÊÁöä ǦǼÀÂɾä ǦŸǪÒöä

¦**Graphic formula** ǦǼɸÆǴŧä Ǧ8ǼÔöä



¦**Chemical name** ȗǝÆȶǼÒöä ȴèɍä

D-*threo*-(–)-2,2-Dichloro-*N*-[*β*-hydroxy-*α*-(hydroxymethyl)-*p*-nitrophenethyl]acetamide; [*R*-(*R**,*R**)]-2,2-dichloro-*N*-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide; CAS Reg. No. 56–75–7.

ǦæøÀȓ ǒÀȒǼæ ȿÜ ǦÁǻÀɳø ǒÀȒǼæ БÜ ȷɀŸöä ǦɕÆȝ ǦöȿÀÛǪɳ ğÀǶǼÀö ȿÜ ǦÁÀæÜ ¢Ǥȉ ğäøɀŸæ ¦**Description** Ȥòɀöä
.ǦǶǝäÀöä ǨÆȝ ǕБøɀŸæ ȧɀǶÊɳ ȿÜ ÀÁòǪö

ǕR ȯɀÒŸȡ ƙŸǼæȿƎöäȿ TS(ȯ/ȟ750~) ȯɀɸÀǮǪä Ž ȷÀæȿǾöä Àǧ ǕöÀŧä Ž ȷÀæȿǾöä ǴǼǶȉ ¦**Solubility** ǦǼɸÀæȿǾöä
.R ƘǬɉäȿ R ȳøɀɀȿøɀŸÒöä Ž ȷÀæȿǾöä ǴǼǶȉ

.Ȼɀǿǵ ǻÀȒɳ ¦**Category** ǦÀÁöä

.ǒɀȒöä ȡɳ ǦǼŧʈ ÛǺÆǼǲ ǦŌŸ8ɳ ǦÁȿÀǵ Ž ȯɀÒǼÆÀǶäøɀŸÒöä ȘÀǵ Æƶ ¦**Storage** ȡÁÂǺǪöä

R ȯɀɸÀǮǪä Ž ȯɀŸǂä ȷɀÒÁȿ .Àɳ ȧäØɳ ȯɀÒǼÆÀɳäøɀŸÒŸö ¦**Additional information** ǦǼɀÀȓÜ ğÀɳɀŸǨɳ
.levorotatory ÀÁȿǼǪöä ȻÀÊÁÜ R ŌǼǮÁǪä ğÀǪǼèÜ Ž ȯɀŸǂäȿ dextrorotatory ÀÁȿǼǪöä ȡȶǼɳ (ǒÀŧä ţȿÂøÀɳ) ȤǼÀɀɾä

REQUIREMENTS ƘǦǶǈƱƙǆǅ!ƒ

ȡȝ ǼÁÂÁ ɍȿ %97.0 ȡȝ ŌŌÁ ɍ Àɳ ȝŸȝ ȯɀÒǼÆÀɳäøɀŸÒöä Ȼɀǫȝ ¦**General requirement** ȳÀǨöä ÆŸÛǪŧä
.ǦÀǶŎä ǥÀŧä БÜ ţɀǲÀöÀæ ǦæɀÊʈ Û$C_{11}H_{12}C_{l2}N_2O_5$ ȡɳ %02.0

:**Identity tests**

A. B ... C ...

A: ... (Spectrophotometry in the infrared region" (43 ...) ... reference spectrum ... RS ...

B: ... "Related substances" ... B ... C.

C: ... 151 °م.

Specific optical rotation: ... 50 ... R $[a]_D^{20 C} = +18.5 \text{ to } +21.5°$.

Free chlorides: ... 0.50 ... 20 ... 10 ... 5 ... 1 TS (130~) ... "Limit test for chlorides" (124 ... 0.5 ...

Solution in ethanol: ... 0.50 ... 10 ... TS (750~) ...

Sulfated ash: ... 1.0 ...

Loss on drying: ... 105 ... 10 ...

pH value: ... 0.05 ... 10 ... R ... 5.0 - 7.5.

Related substances: ... "Thin-layer chromatography" (84 ...) ... R2 ... 9 ... 1 ... R ... 5 ... 3 ... 20 ... 1 ... TS (750) ... (A): ... 0.20 ... 1 ... (B): ... 0.20 ... (C): ...

[illegible] 1 [illegible] RS 254) [illegible] 5 [illegible] 105 [illegible] .B [illegible]

[illegible] 100 [illegible] 20 [illegible] **Assay** [illegible] 1 [illegible] 100 [illegible] 10.0 [illegible] $C_{11}H_{12}C_{12}N_2O_5$ [illegible] 278 [illegible] RS [illegible] 0.03 ± 0.60 [illegible]

ØØØØØ

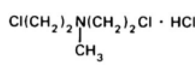
CHLORMETHINI HYDROCHLORIDUM

Chlormethine hydrochloride [illegible]

$C_5H_{11}C_{12}N$, HCl **Molecular formula** [illegible]

192.5 **Relative molecular mass** [illegible]

Graphic formula [illegible]



Chemical name [illegible]

2,2′-Dichloro-*N*-methyldiethylamine hydrochloride; 2-chloro-*N*-(2-chloroethyl)-*N*-methylethanamine hydrochloride; CAS Reg. No. 55-86-7.

[illegible] **Description** [illegible]

TS [illegible] 750~) [illegible] **Solubity** [illegible]

Antineoplastic [illegible] **Category** [illegible]

[illegible] **Storage** [illegible]

[illegible] **Additional information** [illegible]

.hygroscopic ǦǴùÀǪÊῃ

REQUIREMENTS ƘǴǖǮƙdž!ƒ

ǼǺÂǺ ɍʂ %98.0 ȸȝ ŌŐǺ ɍ Åῃ ɁŸȝ ƙǯǼῃǿζŸÒǒ ǼǺǿζŸȭʂǿǼǼ Ƀζǫʒ :**General requirement** ȳÅǰǒ ǼŸÛǪʈǟ .ǦǼǝÅῃƳǒ ǥåÅʈǟ Ƃǖ ʈζǱǍǒÅǣ Ǧǣζ ÊҬ Û$C_5H_{11}Cl_2N$, HCl ȸῃ %101.0 ȸȝ

:**Identity tests** ƕǐŇǌǈǁ ǀ ƐƥƑǴǂƢƐ

potassio-mercuric Ʉȅ Àǩζ Ǵǒ ȨǴǝÂǒ ǼǺáζǺ ȯζŸɫ ȸῃ Ōῃ 0.02 ȣ ÅȒǺʂ ǒÅʈǟ ȸῃ Ōῃ 5 Ž ȟ 0.05 ǟ ǟǾǺ :A .ǦȀÒǒ ɈζŸǣ ǦǣÅȅǿ ǰǪǺ Üiodide TS

ÛǯǍǺɫ .ǿÅǴǪǹǟ ǟζǴǪǖ Ž ɁζǪɨǟ VS (ȯ/ȯζῃ 0.1) ȳζǺáζÔǒ ǧÅǺŸȅζǫǭ ȯζŸɫ ȸῃ Ōῃ 1 Ƃǖ ȟ 0.1 ȣ ÅȒǺ :B .ÀΣǟ áζǫǒǒ ɈζǑ ɁŌǴǺ ÜTS áζǫǒǒ ȯζŸɫ ȸῃ ǥÀÛȩ 1 ȣ ÅȒǺʂ ÛǦȝÅȅ 2 ǥǼῃ ǿǟÀŌǪȅƳǒ ȭÀǪɫ .ŌȮÅǪǒ ȝῃ °ȳ 110 ǦǟǟÀȩ ǿÅǮÔǫɍǟ ǥǿǟÀǵ ǴǱǿá ῃŸǴǩ :C

ǼǫÊȭǖ ɄǝÅǺǭ ȸῃ ƂÅƪǟ R ǒÅʈǟ ȸῃ Ōῃ 10 Ž ȟ 0.10 ÂǫȭÀǪǣ ȯζŸɨǟ ɈζÒǺ :**Clarity of solution** ȯζŸɨǟ ǒÅÀȍ .ǼǫζÅȍ ɈζǟÀÒǒ

.ȟ/ῃŸῃ 1.0 ȸȝ ǼǺÂǺ ɍ :**Sulfated ash** ǨÅŸÊʈǟ áÅῃÀǒǒ

Determination of water by ÀÎǫζ ȯǿÅȭ ǦŌǺÀÛǣ ǒÅʈǟ ƙǫǨ" ɈǟζǺȝ ǨƠ ȣζȍζῃ ζȽ ÅȶȭȸǒǨɫ :**Water** ǒÅʈǟ ǒÅʈǟ ɁζǪɫ ǼǺÂǺ ɍ ÜǥåÅʈǟ ȸῃ ȟ 1 ǦǟǟÀȩ ȯÅȶǨǪȅÅǣ Û(145 ǦǶÅÔǒǒ Û1 ǼŸÒǟ) A ǦŌǺÀÛǒǒ Û"Karl Fischer method .ȟ/ῃŸῃ 5.0 ȸȝ

5.0 - 3.0 ÛŌῃ/ῃŸῃ 2.0 ȯζŸɫ ǒÅȽÅǣ ῃŸǴǺ :**pH value** ǒÅȽÅǴǒǒ Ǧȶǫȩ

ȯζǫÅǯǺ/ȳζǫȅÀǩζǴǒ ǼǫÊȭʂǿǼǼ ȯζŸɫ ȸῃ Ōῃ 15 ÛǦǫùζǴȒῃ ǦǫʂàζῃÛȟ 0.20 ǦǟǟÀȩ Ƃǖ ȣ ÅȒǺ :**Assay** ǦÊǺÅŌʈǟ ȳÅƥ ɁŸȝ ȯζŸɨǟ ÀÁǴǩʂ ǦȝÅȅ 2 ǥǼῃ ɄȝζǱÀǒǒ ɈÀÀƨÅǣ ŌȶǨǺ ƵǯŌῃ ǨƠ ɁŸȣɫ .ǒÅʈǟ ȸῃ Ōῃ 15ʂ VS (ȯ/ȯζῃ 1) Ōῃ 50ʂ TS (ȯ/ȟ 1000~) ŌǺÀǪǺǒ Ȁ ƥ ȸῃ Ōῃ 3 ȣ ÅȒǺʂ ÛǒÅʈÅǣ Ōῃ 150 Ƃǖ ƵÅƩ .ȼȶǱǵ ƵÔǫ ɁǿǪǵ ɄǝÅῃ Ž ǥǼǝǟÂǒǒ ǦȒÅǒǒ ǧǟÀǪǫ ÀǺǨǩʂ ǒÅʈÅǣ ǦǣÅȅÀǒǒ ŌÊȣɫ .ǴǖÀǺʂ ǥζŌǣ ȒƩ .VS (ȯ/ȯζῃ 0.1) ǦȒÅǒǒ ǧǟÀǪǫ ȯζŸɫ ȸῃ ǧÅǺŸȅ ȯζŸɫ ȸῃ Ōῃ 2.5 ȯÅȶǨǪȅÅǣ ÛVS (ȯ/ȯζῃ 0.1) ȳζǫǫζῃʝǟ ǧÅǫǼȅζǫǭ ȯζŸǶῃ ǧɍÅÊȣǒʂ ǦǵÅȉÀǒǒ ʈζȶƒ 0.1) ǦȒÅǒǒ ǧǟÀǪǫ ȯζŸɫ ȸῃ Ōῃ 1 Ōȭ .ÀǨÎȶȭ (ȯ/ȟ 45) ferric ammonium sulfate TS ŌǺǼǺΣǟ ȳζǫǫζῃǖ .$C_5H_{11}C_{12}N$, HCl ȸῃ ῃŸῃ 6.417 ùζÅÒǺ VS (ȯ/ȯζῃ

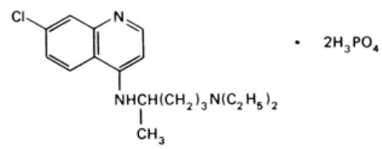
CHLOROQUINI PHOSPHAS

Chloroquine phosphate

$C_{18}H_{26}ClN_3\ 2H_3PO_4$:**Molecular formula**

515.9 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

7-Chloro-4-[[4-(diethylamino)-1-methylbutyl]amino]quinoline phosphate (1:2); *N*[4]-(7-chloro-4-quinolinyl)-*N*[1],*N*[1]-diethyl-1,4-pentanedi-amine phosphate (1:2); CAS Reg. No. 50-63-5.

:**Description**

TS (750~) 4 :**Solubility**

.R R

:**Category**

:**Storage**

:**Additional information**

215 194

.215 194

REQUIREMENTS

%98.0 :**General requirement**

$C_{18}H_{26}ClN_3, 2H_3PO_4$ %101.0

:**Identity tests**

VS 0.01 10 :A

.ÀǪʐɀǷȀǷ 360ȘǷȀǷ 240 ƙǻ Ȁʐ ǼȽȀÎÀ ȀʐǼȀȝ ÛÀǪʐɀǷȀǷ 343Ș ÀǪʐɀǷȀǷ 329 ÛÀǪʐɀǷȀǷ 257 ǴǻǻÀȩ ǼȀȝ ǴȽȶȚȝÛ ɁǿǼ

ȴȅ2 ȄȽǑǩ ğǻǨƊɀǵ ȯȀȶȞǪȅǻ ǑȒȀȽ) ƃǻɀǪǻ ɁǷȝ Û0.37Ș 0.32, 0.29 ǾǾȽ ǯǻɀʐȷǻ ȯǻɀǜÛ ǼȀȝ ğȀȍȀȶǪǻ ɉɀǑǩȘ

ƃÛ ÀǪʐɀǷȀǷ 257 ǼȀȝ ȴȅ 1 ǴǷȀǺǯǻ ǴǑǴÛǒ îȀȶǪǻ ǴǴÊǷ ɉɀǑǩȘ .(ȴȅ 1 ǴǷȀǺǯǻ ğȀǑǴÛǒ ğȀȍȀȶǪǻ ǼÊƠȘ ğȀȅȀȽǑǷǒ

0.86 ƙǻ ÀǪʐɀǷȀǷ 343 ǼȀȝ îȀȶǪǻ ƃÛ ÀǪʐɀǷȀǷ 329 ǼȀȝ îȀȶǪǻ ǴǴÊǷȘ Û0.85Ș 0.77 ƙǻ ÀǪʐɀǷȀǷ 343 ǼȀȝ îȀȶǪǻ

.0.95Ș

A ǑȝȀȀǪǻ ɄÛȞÀ ÜTS (ȯ/ȟ 130~) ǬÀÀǪȀǻ Ȁþ ȡʐ Ǒʐ 3 Ǒʐ/ʐǷʐ 20 ÂȽǬÀǪǻ ȯɀǷȚ ȡʐ Ǒʐ 1 ƃÛ ȣȀȒÀ :B

ğȀǴǬÀȶ ÂȽɯ ǑȝȀȀǪǬ "General identification tests ǴʐȀȞǒǻ ȣǻÀȞǪȅɍǻ ğǻǿȀǴǪɳǻ" ɉǻɀȝ ǨƠ ȣɀȍɀȶǻ

.(122 ǴɄȀÔǒǻ Û1 ǼǷǑǻ) ğȀÀÊȤɀǪǿȘȷǻ

ÛǴȉÀȽ .Ts (ȯ/ȟ 7) ȯɀȽɀȘÀǷ ɄǷǷǷ ȯɀǷȚ ȡʐ Ǒʐ 5 ǒȀȶǻ ȡʐ Ǒʐ 20 Ž ȟ 0.05 ÂȽǬÀǪǻ ȯɀǷȚ ƃÛ ȣȀȒÀ :C

ǴƊǿǻ ʐǷǴǩ .R ȤȀƊɀȟ ÛȀǑǷȽÊǒǻ ǴʐǷȽ ǻɀɀ ǴǻȀȅÀǒǻ ȤȀƊȽ ÛɉɀǷǒǻ ǴȥǼȝ ǴǵȀìÀǒǻ ǴǴǑǩ ɁǿǪǵ ǒȀȶǻ ǴǻȀȅÀǒǻ ǑÊȣȽ

.(ğǻÀǑȽǻ) °ȳ 207 ǴǻǻÀȩ ÛǿȀȚǑǷɍǻ ǵǿǻÀǵ

.ȟ/ʐǷʐ 20 ȡʐ ÀǯǬÛ ǼǑÀÀ ɍ Ü°ȳ 105 ǼȀȝ ǨǻȀǯǒǻ ɉàɀǒǻ ɁǿǪǵ ȤȀƊȽ :**Loss on drying** ȤȽȀƊɀǪȀǻ ǼǑÀǒǻ

.4.5 - 3.5 ÛǑʐ/ȟ 0.10 ÂȽǬÀǪǻ ȯɀǷȚ ǒȀȽȀǻ ʐǷǴÀ :**pH value** ǒȀȽȀǴǒǻ ǴȶȽȩ

ǴǑȽȩÀǒǻ ǴǑǴÛǒ āǻÀÎǪȅǻ" ɉǻɀȝ ǨƠ ȣɀȍɀʐ ɀȽ Ȁȶǭ ǿȀǴǪɳɍǻ ȨǴÛÀ :**Related substances** ǴǑȀÎȶǻ ǻǻɀȶǻ

5 ȡʐ ǰÀÂʐȘ ǴǷǫȣʐ ǵǻȀȶǭ R2 ȀǑȽǷȽÊǒǻ ǴʐǷȽ ȳǼǺǪÊȽȘ Û(84 ǴɄȀÔǒǻ Û1 ǼǷǑǻ) "Thin-layer chromatography

ȨǻȽÛȽ .ǬÀɄǪʐ ǿɀÛǭ R ƙʐǷȽǯÀÛ ɄǻÀǷ ȡʐ ȽȶƊɀǵ 1Ș R ɉȀÊǑȽȽɀǷǑȽÊǒǻ ȡʐ ȳɀƊɀǵ 4 ÛR ȳǿɀɀȘǿɀǷǑǒǻ ȡʐ ȳɀƊɀǵ

Ǒʐ 1 Ǒǭ Ž ǿȀǴǪɳɍǻ ǵǻȀʐ ȡʐ ʐǷʐ 40 Ƀɀȝ :(A) ȯɀǷɉǻ ÛƙÀǪǻ ƙȯɀǷȚ ȡʐ ÀǪǬȘÀǑʐ 5 ǴɄȽȀÔǒǻ ɁǷȝ ȸǷÔÀÀʐ

ǬÀǪǩ ÛāǻÀÎǪȅɍǻ ǵƊɀǵ ȡʐ ǴɄȽȀÔǒǻ ȶÂǿǷ ǼȞǻȘ .Ǒʐ 1 Ǒǭ Ž ǿȀǴǪɳɍǻ ǵǻȀʐ ȡʐ ʐǷʐ 0.80 Ƀɀȝ (B) ȯɀǷɉǻȘ

ǰǪǩ ǴȞǑǻ ǴÀÛ ɉɀǑǩ ɍ .(ÀǪʐɀǷȀǷ 254) ǴȽƊÊÀÀǴǒǻ ǻɀɀ ǴȞìȷǻ Ž āǻÀÎǪȅɍǻ ÙÛƯ ǑɄÀȽȘ ÙÛƯ ÛǒǻɀȚǻ Ž ȤƊɀǪǒ

.B ȯɀǷɉǻ ȡʐ ǴΘÀÀǒǻ ǬǷǩ ȡʐ ǵǼì ÀǯǬÛ ÛǴȽÊȽǝÀǒǻ ǴȞǑǴǒǻ ǒÀǯǪȅȀǻ ÛA ȯɀǷɉǻ ȡʐ

ǵǼȝȀÊʐ R1 ɄƊɀǷǯǒǻ ǬȽǪȅȷǻ Ȁþ ȡʐ Ǒʐ 20 Ž ÛǴȽüɀǴȒʐ ǴǷȘàɀʐ Ûȟ 0.23 ǴǻǻÀȩ āǻǿÀ :**Assay** ǴÊÀȀǑȶǻ

ÀÀȀȞȽ .R ɉȀÊǬɀÀǼǒǻ ȡʐ Ǒʐ 20 ȣȀȒȽȘ ǻǻȽ Û(Ʉȝɀ ƊÀÀǒǻ ɉÀÀÀǝȀǻ ǑȶȞÀ ȤȀǑʐ ǨƠ ƙǺÊǪǒǻ ǑȒȀȽ) ƙǺÊǪǒǻ

Non - ɄǝȀʐǷǒǻ ÙȅɀǒǻŽ ǵÀÀȞȶǻ" ɉǻɀȝ ǨƠ ȣɀȍɀʐ ɀȽ Ȁȶǭ VS (ȯ/ȯɀʐ 0.1) ǬÀǿɀǷǬǨǴǒǻ Ȁþ ȯɀǷɄʐ

(ȯ/ȯɀʐ 0.1) ǬÀǿɀǷǬǨǴǒǻ Ȁþ ȯɀǷȚ ȡʐ Ǒʐ 1 Ǒǭ .(142 ǴɄȀÔǒǻ Û1 ǼǷǑǻ) A ǴǑÀÀÛǒǻ Û"aqueous titration

.$C_{18}H_{26}ClN_3, 2H_3PO_4$ ȡʐ ʐǷʐ 25.79 ǜɀȀǑÀ VS

[illegible]

Additional requirement for Chloroquine phosphate for parenteral use

.(56 [illegible] 4 [illegible]) "Parenteral preparations [illegible]" [illegible]

[illegible]

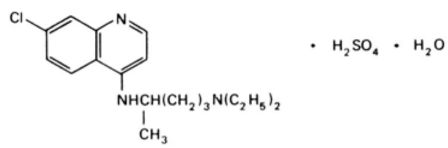
CHLOROQUINI SULFAS

Chloroquine sulfate [illegible]

$C_{18}H_{26}ClN_3, H_2SO_4, H_2O$:**Molecular formula** [illegible]

436.0 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

7-Chloro-4-[[4-(diethylamino)-1-methylbutyl]amino]quinoline sulfate (1:1) monohydrate; *N*[4]-(7-chloro-4-quinolinyl)-*N*[1],*N*[1]-diethyl-1,4-pentanediamine sulfate (1:1) monohydrate; CAS Reg. No. 6823-83-2.

.[illegible] :**Description** [illegible]

[illegible] (750~ [illegible]) [illegible] 3 [illegible] :**Solubility** [illegible]

.R [illegible] R [illegible]

.[illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

.[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]

.[illegible] $C_{18}H_{26}ClN_3, H_2SO_4$ [illegible] %101.0

:**Identity tests** ƕĭŇǌŇǁƐ ǀ ƐƥƑĠĦƠǀƐ

VS (ȯ/ȯzƞ 0.01) ǬÀøzŸõşøÆŒTā Ȑ Ƥ ȯzŸȚ Ž Ōƞ/ÿāÀdşÀȮƞ 10 ÂƐõÀQæ ȯzŸǂ î ÀÔQƞɍā ȤƐù ɃÆGA :A 329 ÛÀQƞzƥÀƥ 257 ǦææÀǝ ÆA3 ǦƐȶȚ3Ǘ ǧÀòÀÔQƞā 3 ÀQƞzƥÀƥ 360ş ÀQƞzƥÀƥ 240 ƙæ Àƞ ǯāzƞɉā ȯāzùǗ Ž ÆŁÀÎA ÀƞÆA3 ŌȒÀǂ) ƃāzQöā ʔŸ3 Û0.46ş 0.39, 0.44 ǦææÀǝ ȻǾȽ ǯāzƞɉā ȯāzùǗ ÆA3 ǧÀòÀȶQöā ɈzȮǩş .ÀQƞzƥÀƥ 343ş ÀQƞzƥÀƥ 1 ǦƥÀǺǯæ ǦŌǦù î ÀQ ǦGÊƥ ƞŸǦǩş .(ȴè 1 ǦƥÀǺǯæ ǧÀŌǦÛō ǧÀòÀȶQöā ÆÊƠş ǧÀèÀƐŌŸō ȴè 2 ȀƐŌǩ ÀAƳǹ ȯÀȶȞQèā î Àȶ Qöā ƃǗ ÀQƞzƥÀƥ 329 ÆA3 î Àȶ Qöā ǦGÊƥş 0.98ş 0.83 ƙæ Àƞ ÀQƞzƥÀƥ 343 ÆA3 î Àȶ Qöā ƃǗ ÀQƞzƥÀƥ 257 ÆA3 ȴè .1.03ş 0.94 ƙæ Àƞ ÀQƞzƥÀƥ 343 ÆA3

General ǦƞÀȞöā ȣāÀȞQèɍā ǧāøÀGQǹā" ɈāzA3 ǨƠ ȣzòzȶā A Ō3ÀAQöā Ōƞ/ȟ 0.05 ÂƐõÀQæ ȯzŸȚ ɄÛȞA :B .(123 ǦȞɄÀÔöā Û1 ÆŸŌā) ǧÀAŸÊŸō Âƃȶƞ Ō3ÀAQō "indentification tests

ÛǦĩÀǂ .ōÀȶā ȸƞ Ōƞ 20 Ž ȟ 0.05 ÂƐõÀQæ ȯzŸȚ ƃǗ TS (ȯ/ȟ 7) ȯzƐzşÀQƥ ɄQŸQ ȯzŸȚ ȸƞ Ōƞ 5 ȣÀȒA :C ǥøāÀǵ ǦDZøǻ ƞŸǦǩ .R ÀȮƐŸƐÊöā ǦƞƳȽ ȤǭDzƞ ȧzz ǦæÀèÀöā ȤǭDzǩş ǦǵÀìÀöā Ɉzō ȯāşà ʔøQǵ ǒÀȶæ ǦæÀèÀöā ŌÊȣǂ .(ǧāÀȮƐæ) °ÿ 207 ǦææÀǝ øÀȢÔƥɍā

.ȟ/ƞŸƞ 1.0 ȸ3 ÆAÂA ɍ :**Sulfated ash** ǨÀŸÊȶā ǻÀƞÀöā

0.6 ʔÆȞQAɍ) ȐÀǺÀƞ Ȕȣȓ ǨƠ °ÿ 105 ÆA3 ǨæÀǯöā Ɉàzöā ʔøQǵ ȤÀƻ :**Loss on drying** ȤƐÀDzQöÀæ ÆŌÀöā .ȟ/ƞŸƞ 50 ȸƞ ÀǯōǗ ɍş ȟ/ƞŸƞ 30 ȸƞ ŌǝǗ ÆŌÀA ɍ Ǘ(ȨGəà ȴŸƞ 5 ǦææÀǝ şǗ ȯÀȮèÀæ zŸƐõ

.5.0 - 4.5 ÛŌƞ/ȟ 0.10 ÂƐõÀQæ ȯzŸȚ ǒÀȽÀæ ƞŸGA :**pH value** ǒÀȽÀGöā ǦȶƐǝ

ǦŌƐǝÀöā ǦŌǦÛöā āāÀÎQèā" ɈāzA3 ǨƠ ȣzòzƞ zȽ Àȶõ øÀGQǹɍā ȨǭÛǂ :**Related substances** ǦōÀÎȶā ǻāzȶā 5 ȸƞ ǰAÀƞş ǦŸǥȣƞ ǥǻÀȶõ R2 ÀȮƐŸƐÊöā ǦƞƳȽ ȯÀȶȞQèÀæ Û(84 ǦȞɄÀÔöā Û1 ÆŸŌā) "Thin-layer chromatography ȨǭÛǂ .õǭȞɄQƞ øzÛõ R ƙƞƳƐǯAǗ ɄəÀAǫ ȸƞ ǂȶDzǵ 1ş R ɈÊȮȽzŸȮƐÊöā ȸƞ ÿzDzǵ 4ş R ÿøzzşøzŸȮöā ȸƞ ÿzDzǵ ȯzŸǂāş Ōƞ 1 Ōõ Ž øÀGQǹɍā ǥǻÀƞ ȸƞ ƞŸƞ 40 Ƀz3 :(A) ȯzŸǂā ÛȯzŸȚ 2 ȸƞ ÀQōşÀȮƞ 5 ǦȞɄƐÀÔöā ʔŸ3 ƳÔÀAƞ ȤDzQō õÀQǂ ÛāāÀÎQèɍā ǥǨDzǵ ȸƞ ǦȞɄƐÀÔöā ȶÂøƥ ÆȞæş .Ōƞ 1 Ōõ Ž øÀGQǹɍā ǥǻÀƞ ȸƞ ƞŸƞ 0.80 Ƀz3 :(B) ÛA ȯzŸǂā ȸƞ ǰQÀǩ ǦȞŌæ ǦAǗ ɈzȮǩ ɍ .(ÀQƞzƥÀƥ 254) ǦƐDzÊÀAGöā ȧzz ǦȞì ɉā Ž āāÀÎQèɍā ÙÛƯ ȰɄÀǂş ǒāzTā Ž .B ȯzŸǂā ȸƞ ǦɵÀAöā ǬŸǩ ȸƞ ǥÆì ÀǯōǗ ÛǦƐÊƐəÀöā ǦȞŌGöā ǒÀAǯQèÀæ

ǥÆ3ÀÊƞ R1 ɄDzŸǯöā ǬƐQƐèɉā Ȑ Ƥ ȸƞ Ōƞ 20 Ž ÛǦƐùzǦȒƞ ǦƥşàzƞÛȟ 0.4 ǦææÀǝ āāǾǂ :**Assay** ǦÊAÀŌȶā ǦÛèāzæ ÀĿÀȞǂ .R ɈÀÊõzAÆöā ȸƞ Ōƞ 20 ȣÀȒǂş ǻĦǂ Û(Ʉ3zDZÀöā ɈAÀƨÀæ ŌȶȞA ȤǯŌƞ ǨƠ ŌȒÀǂ) ƙǺÊQöā

Non ƟǝǻŋŸöä Ùèǽöä Ž ǵÀǺǺŤţä" ǰåǽǺȝ ĶƠ ȣǽòǽŋ ǽĿ ǺŧŎ VS (ò/òǽŋ 0.1) ǬǺøǽŸŎƘƓöä ȒƥòǽŸŢ 0.1) ǬǺøǽŸŎƘƓöä ȒƥòǽŸŢ ȸŋ Ŏŋ 1 ŎŎ .(142 ǦHǺÔöä Û1 ǼŸŎä) A ǦŎǺÀÛöä Û"aqueous titration

.$C_{18}H_{26}ClN_3$ H_2SO_4 ȸŋ ŊŸŋ 41.8 ùǽǺŎǺ VS(ò/òǽŋ

Ǐ øǽŝƟǁ üƑŽyŧƨ úǁ ƔơyǂŽǁ ǅŤǀǋǋþǋǂǁ ǀƑǂƨ üǖǓ ǏȝƑŢǝ ƒǂǕǂŽ

Additional requirement for Chloroquine sulfate for parenteral use

.(56 ǦHǺÔöä Û4 ǼŸŎä ÀŢǿä) "Parenteral preparations ǦǼŎƩä ǧäÀȒHǪÊţä" ǵǻşǺǽǻ Ž ǻøş Ǻţ ǼǼǅǪÊǺ

ØØØØØ

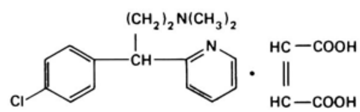
CHLORPHENAMINI HYDROGENOMALEAS

Chlorphenamine hydrogen maleate ǅŤǅŽƑǂȝþǋǂǁ ǅŤǖǋþơǂǰ ǀƑǂǁƑǅŽ

$C_{16}H_{19}ClN_2$, $C_4H_4O_4$ or $C_20H_{23}ClN_2O_4$ ¦**Molecular formula** ǦǼǺÂƨä Ǧ8ǼÔöä

390.9 ¦**Relative molecular mass** ǦǼƓÊǺöä ǦǼǺÂƨä ǦŸǪÒöä

¦**Graphic formula** ǦǼǿǺǼƓţä Ǧ8ǼÔöä



¦**Chemical name** ƟǝǺǼŧǼÒöä ǈèŗä

2-[*p*-Chloro-*α*-[2-(dimethylamino)ethyl]benzyl]pyridine maleate (1:1); *γ*-(4-chlorophenyl)-*N*,*N*-dimethyl-2-pyridinepropanamine (*Z*)-2-butene-dioate (1:1); CAS Reg. No. 113-92-8.

.Chlorphenamine hydrogen maleate ƙŋǺǼǽøǽŸÒöä ƙǅǽşøǼǼĿ ǧǺǼöǺŋ ¦**Other name** Àňɇä ǈèŗä

.ǦHǝäÀöä ƇǼȝ ÜȒǼǽÜ ɃøǽǺǽ àǽHÊŋ ¦**Description** Ȥòǽöä

ÜR ÿøǽǽşøǽŸÒöäş TS (ò/ȟ 750~) òǽǿǺȝǺɋä Ž āäşǽ ÜöǺţä ȸŋ öäÂǅÜ 4 Ž āäşǽ ¦**Solubility** ǦǼǿǺǽşØöä

.R Ƙǫɉä Ž ǰǺǽşØöä ǴǼHì

.ƙŋǺǪÊŦŸö ǻǺȒŋ ¦**Category** ǦǺÀöä

Ž chlorphenamine hydrogen maleate ƙŋǺǼǽøǽŸÒöä ƙǅǽşøǼǼĿ ǧǺǼöǺŋ ȘǺǵ Ǽȥ ¦**Storage** ȸǺÂǺǪöä

.öǽȒöä ȸŋ ǼǼŧŢ ÛÿǺÒǵǽǽ ǦŎŸ8ŋ ǦǺşǺǵ

ôÀȞǪöä ʔǼö ǼǼȥøǼǩ ƙŋǺǼǽøǽŸÒöä ƙǅǽşøǼǼĿ ǧǺǼöǺŋ ŏøǼǪ ¦**Additional information** ǦǼǽǺȓÜ ǧǺŋǽŸȞŋ

[illegible].

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] **General requirement**: [illegible] %101.0 [illegible] $C_{16}H_{19}ClN_2, C_4H_4O_4$ [illegible].

Identity tests: [illegible]

• [illegible] A [illegible] B [illegible] C [illegible].

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 1 [illegible] 5 [illegible] 1 [illegible] 1 [illegible] TS [illegible] 3.5 [illegible] 1 [illegible] TS [illegible] 10 [illegible]. [illegible] 2 [illegible] 1 [illegible] R [illegible] 25 [illegible] R [illegible].

C: [illegible] 0.5 [illegible] 5 [illegible] 0.2 [illegible] (100~ [illegible]) TS [illegible] 4 [illegible] 25 [illegible] R [illegible] 132 [illegible] R [illegible].

Sulfated ash: [illegible] 1.5 [illegible].

Loss on drying: [illegible] 105 [illegible] 5.0 [illegible].

pH value: [illegible] 20 [illegible] 4.0 - 5.2.

Related substances: [illegible] "Thin-layer chromatography" ([illegible] 1 [illegible] 84) [illegible] R2 [illegible] 5 [illegible] R 3 [illegible] R 2 [illegible] (60~ [illegible]) TS [illegible]. [illegible] 2 [illegible] 2 [illegible] (A): [illegible] R [illegible] 0.10 [illegible] 1 [illegible]. [illegible] (B): [illegible] 50 [illegible] 1 [illegible]

254) ǦĔĐǳÊÀÁĠöä àǶǶ ǦĤì ǰä Ž āäÀÎǪèɍä ÙÛƯ ÒĦǺÀłş ÛöäǶŢä Ž ǷĐǶǪö õÀǪǩ Ûāä ÀÎǪèɍä ǥƘĐǶǵ ȸȵ ǦĦĔÀÔöä
Ȑƥş ƙȵÀÀĔǶ øǶŸÒöä ƂÜ ȷäåǶĦǩ ƙǪŸöä ƙǪĔÊĔǝÀöä ƙǪĦŌĠöä öÀÀǯǪèÀä ÛA òǶŸǂä ȸȵ ǰǪÀǩ ǦĦŌæ ǦÀÜ ȷǶÒǩ ɍ .(ÀǪȵǶǵÀǵ
.B òǶŸǂä ȸȵ ǦƟÀÀöä ÕŸǩ ȸȵ ǥÆì ÀǰõÜ Ûmaleic acid ÕĔĔöÀţä

ÀÀÀĦłş R1 ɄĐǶŸǯöä ÕĔǪĔèǰä Ȑƥ ȸȵ Ōȵ 30 Ž ÛĈĔùǶĜȒȠ ǦǵşàǶȵ Ûȟ 0.4 ǦääÀȩ āäØł ¦**Assay** ǦÊÀÀŌţä
ɄǝÀȵŸöä ÙèǶöä Ž ǥÀÀÀĦţä" ȷäǶÀȝ ǨƠ ȣǶòǶȵ ǶȽ Àŧõ VS (ò/òǶȵ 0.1) ÕÀøǶŸõƘĠöä Ȑƥ òǶŸȚ ǦÛèäǶæ
0.1) ÕÀøǶŸõƘĠöä Ȑƥ òǶŸȚ ȸȵ Ōȵ 1 Ōõ .(142 ǦĦÀÔöä Û1 ÆŸŎä) A ǦŌÀÀÛöä Û"Non-aqueous titration
.$C_{16}H_{19}ClN_2$, $C_4H_4O_4$ ȸȵ ȠŸȵ 19.54 ùǶÀÒÀ VS (ò/òǶȵ

Ïǳ̄ƟÏÏ ǚĘĎǮƚƨǘÏ ƔǢƴĎǮÏÏ ĎǮĭĎǮǳǮƹǮǂÏÏ ĎǮĭǙǸƥǭǮǰ ǀǮĭÏĘĎǮ ǚǙǓ ƕǮǯĘȚǭ ǀĘǂǓĦĎǮ

Additional requirements for Chlorphenamine hydrogen maleate for parenteral use

.(56 ǦĦÀÔöä Û4 ÆŸŎä ÀŢǪä) "Parenteral preparations ǦĔÕƩä ǧäÀȒĦǪÊţä" ǥåşÀǶǹ Ž åøş Àţ ÆĔĐǪÊǩ
øÀĠǪǹɍä" ȷäǶÀȝ ǨƠ ȣǶòǶȵ ǶȽ Àŧõ øÀĠǪǹɍä ĘǜÛł ¦**Bacterial endotoxins** ǦĔȵǶǪÀƨä ǦĔŸǹäÆöä ǧÀǵÀÀÀØöä
ɍ Ü(ǦÀÂĔŸƠǭä ǦĦĜÛöä Ž 30 ǦĦÀÔöä Û5 ÆŸŎä) "Test for bacterial endotoxins ǦĔȵǶǪÀƨä ǦĔŸǹäÆöä ǧÀǵÀÀÀØöä ŌĐǶǰ
.ȠŸȵ 1 Ōõ Ž RS ɄŸǹäÆöä ȷÀÀÀØöä ȸȵ ǦĔõşå ǥÆǵş8.8 ȸȵ ÀǰõÜ ɃǶȜ

ØØØØØ

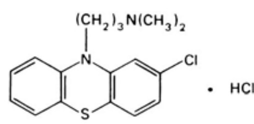
CHLORPROMAZINI HYDROCHLORIDUM

Chlorpromazine hydrochloride ĎǮĭȐĘĎǮǹƥĜƥǹǂÏÏ ǭǮƥǹǂÏǹƥǭǮǰ

$C_{17}H_{19}ClN_2S$, HCl ¦**Molecular formula** ǦĔÀÀÂƨä Ǧ8ĔÔöä

355.3 ¦**Relative molecular mass** ǦĔĜÊÀöä ǦĔÀÀÂƨä ǦŸǪÒöä

¦**Graphic formula** ǦĔǵÀĔĜţä Ǧ8ĔÔöä



¦**Chemical name** ɄǝÀĔŧĔÒöä Ǆèɍä

2-Chloro-10-[3-(dimethylamino)propyl]phenothiazine monohydrochloride; 2-chloro-*N*,*N*-dimethyl-10*H*-phenothiazine-10-propanamine monohydrochloride; CAS Reg. No. 69-09-0.

.ǦĦǝäÀöä ǶĔÀǹ ÜǶĔÀǹ ɄǶÀõ ȐĔäÜ şÜ ȐĔäÜ ɃøǶǩæ àǶĦÊȵ ¦**Description** ǶòǶöä

[illegible] R [illegible] TS (750~ [illegible]) [illegible] 0.4 [illegible] **Solubility** [illegible]
[illegible] R [illegible].

[illegible] **Category** [illegible].

[illegible] **Storage** [illegible].

[illegible] **Additional information** [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] 98.0% [illegible] 101.0% [illegible] $C_{17}H_{19}ClN_2S$, HCl [illegible].

Identity tests [illegible]:

- [illegible] A [illegible] B [illegible] C [illegible] D [illegible].

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] *reference spectrum* [illegible] RS [illegible].

B: [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) [illegible] Kieselguhr R1 [illegible] 10 [illegible] 2-[illegible] [illegible] R [illegible] 5 [illegible] macrogol 400 R [illegible] 85 [illegible] R [illegible] 2 [illegible] R1 [illegible] 2 - [illegible] R [illegible] 100 [illegible] R [illegible] 1 [illegible] 2.0 [illegible] (A): [illegible] R [illegible] 2 [illegible] 2 [illegible] 1 [illegible] RS [illegible] 2.0 [illegible] (B): [illegible] (365 [illegible]) [illegible] TS [illegible] 2 [illegible] A [illegible]

.B ϙζŸǂǡ ȸ ǦƟǻǚǡ

ǦŊǻǛǚǡ Ȣ ǡǺǛǪèɍǡ ǧǡøǺǪǹǡ" ȷǡζǺǯ ǨƠ Ȣ ζòζƫ B Ǭǯǻǻǚǡ Ǭŋ/ȟ 0.1 ǺǹǭǺǩ ȻǾǚǡ ϙζŸǂǡ ɄǛǺ :C
.(121 ǦǶǻÔǚǡ Ǜ1ǼŸǛǡ) ǧǡǼǺøζŸǛǾ ǺǭƝ Ǭǯǻǻǭ "General identification tests
.°ÿ 196 ǦǡǺǫ øǻȚÔǫɍǡ ǦDZøǻ ŊŸǨ :D
.ȟ/ŊŸŋ 1.0 ȸǯ ǼǺǺ ɍ :**Sulfated ash** ǨǺŸÊƫǡ ǻǺŋǺǚǡ
.ȟ/ŊŸŋ 5.0 ȸŋ Ǻǯǭǜ ǼǬǺǺ ɍ Ǜ°ÿ 105 Ǽǯ ǨǡǺǯǚǡ ȷàζǚǡ ɁøǪǵ ȤǺDzǺ :**Loss on drying** ȤǺDzǪǭǻ ǼǬǺǚǡ
.5.0 - 4.5 ǛǯǡǺǜ ǬÒÎǡ ǺȒǶȟ ǛǬŋ/ȟ 0.10 ǺǭǺǺǪ ϙζŸȚ ǒǺȽǺ ŊŸǢ :**pH value** ǒǺȽǺǢǚǡ ǦƭǼę
ǦǬęǺǚǡ ǦǬǦǛǚǡ ǡǡǺÎǪèǡ" ȷǡζǯ ǨƠ Ȣ ζòζŋ ζȽ Ǻƭǭ øǺǪǹɍǡ ĘǻǛȽ :**Related substances** ǦǒǺÎƫǡ ǻǡζƫǡ
80 ȸŋ ǰǺǡŋş ǦŸǩȟ ǥǻǺƭǭ R2 ǺÒǼŸǼÊǚǡ ǦŊƳȽ ǿǼǺǪÊǩş (84 ǦǶǻÔǚǡ Ǜ1 ǼŸǛǡ) "Thin-layer chromatography
ĘǻǛȽ .ǭǺǶǪŋ øζǛǭ R ƙŋƳǼǯǺ ɄǡǺǫ ȸŋ ÿζDzǵ 10ş R ȷζǪèɉǡ ȸŋ ÿζDzǵ 10ş R ȷǺÊÒȽζŸÒǼÊǚǡ ȸŋ ǺƭDzǵ
ȸŋ ǺƭDzǵ 95 ȸŋ ȤǒǘŋǼǺØŋ ǰǺǡŋ Ž ǯǡǺǜ ǬÒÎǡ ȸǺǺȒǶȟ ϙζŸȚ 2 ȸŋ ǺǪǒşǺÒŋ 10 ǦǶǻÔǚǡ ɁŸǯ ƳÔǺǺŋ
ϙζŸǂǡş Ǭŋ 1 Ǭǭ Ž øǺǪǹɍǡ ǥǻǺŋ ȸŋ ŊŸŋ 20 Ȼζǯ :(A) ϙζŸǂǡ Ǜ R ƙŋƳǼǯǺ ɄǡǺǫ ȸŋ ÿζDzǵ 5ş R ϙζǫǺǯǼƫǡ
Ž ȤDzǪǭ ǭǺǪǩ Ǜ ǡǡǺÎǪèɍǡ ǥƘDzǵ ȸŋ ǦǶǼǺÔǚǡ ƫǺǫ ǼǺǡş .Ǭŋ 1 Ǭǭ Ž øǺǪǹɍǡ ǥǻǺŋ ȸŋ ŊŸŋ 0.50 Ȼζǯ :(B)
ǙƪǡɁǯ ǦǺǬǡ ǦǺǜ ǬƭȚ .(ǺǪŋζǫǺǫ 254) ǦǼDzÊǺǺǦǚǡ ȧζζ ǦȞǹɉǡ Ž ǡǡǺÎǪèɍǡ ǙǛǙ ǑǶǺǩş ǒǡζȚǡ ȸŋ øǺǼǨ
.B ϙζŸǂǡ ȸŋ ǦƟǻǚǡ ǬŸǨ ȸŋ ǥǼȉ Ǻǯǭǜ ǛǦǼÊǼǡǺǚǡ ǦǨǬǦǚǡ ǒǺǯǪèǺǡ Ǜ(A) ϙζŸǂǡ ȸŋ ǰǪǺǨ ǦǺǬǡ ǦǺǜ ȷζÒǨ ɍ .ȻǼǯǻǬǚǡ
ϙζŸȚ ȸŋ Ǭŋ 10 ȢǺȒǶş R ȷζǪèɉǡ ȸŋ Ǭŋ 200 Ž ǛǦǼǜζǦȒŋ Ǧǫşàζŋ Ǜ ȟ 0.7 ǦǡǺǫ ǡǡǾȽ :**Assay** ǦÊǺǺǬƫǡ
Ȓƥ ϙζŸȚ ǦǛèǡζǡ ǺǺǺǶş TS ȷζǪèɉǡ/ǬǼǯǼƫǡ ǦǼǡǬǨǺǢ ϙζŸȚ ȸŋ Ǭŋ 3ş TS ǬǼǪèɉǡ Ȓƥ/ĘǦǶÂǚǡ ǧǺǪǼèǜ
Ǜ"Non aqueous titration ɄǻŋƳǚǡ Ǚèζǚǡ Ž ǥǺǺǶƫǡ" ȷǡζǯ ǨƠ Ȣ ζòζŋ ζȽ Ǻƭǭ VS (ǒ/ǒζŋ 0.1) ǬǺøζŸǭƘǦǚǡ
ŊŸŋ 35.53 ǜζǺÒǺ VS (ǒ/ǒζŋ 0.1) ǬǺøζŸǭƘǦǚǡ Ȓƥ ϙζŸȚ ȸŋ Ǭŋ 1 Ǭǭ .(142 ǦǶǻÔǚǡ Ǜ1 ǼŸǛǡ) A ǦǬǺǺǛǚǡ
.$C_{17}H_{19}ClN_2S$, HCl ȸŋ

Ǐøǘǂ ǘǡ ǜǡǡŸǂǢ ǥǡ ǡǡǡǡ ǡǡǡǡǡǡǡǡǡǡ ǡǡǡǡǡǡǡǡǡ ǜǡǡ ȟǡǡǡȚǡ ǡǡǡǡǡ

Additional requirements for Chlorpromazine hydrochloride for parenteral use

.(56 ǦǶǻÔǚǡ Ǜ4 ǼŸǛǡ ǺȚǫǡ) "Parenteral preparation ǦǼǬƩǡ ǧǡǺȒǶǪÊƫǡ" ǥǻşǺζǺ Ž ǻøş Ǻƫ ǼǼDzǪÊǺ

øǺǪǹɍǡ" ȷǡζǯ ǨƠ Ȣ ζòζŋ ζȽ Ǻƭǭ øǺǪǹɍǡ ĘǻǛȽ :**Bacterial endotoxins** ǦǼŋζǫǺƨǡ ǦǼŸǹǡǼǚǡ ǧǺǫǺǺǾǚǡ
ɍ Ǜ(ǦǺǼŸƠǵǡ ǦǶǦǛǚǡ ȸŋ 30 ǦǶǻÔǚǡ Ǜ5 ǼŸǛǡ) "Test for bacterial endotoxins ǦǼŋζǫǺƨǡ ǦǼŸǹǡǼǚǡ ǧǺǫǺǺǾǚǡ ǬDZɉ
.ŊŸŋ 1 Ǭǭ Ž RS ɄŸǹǡǼǚǡ ȷǺǺǾǚǡ ȸŋ ǦǼşǻ ǥǼǵş 6.9 ȸŋ Ǻǯǭǜ Ȼζǯ

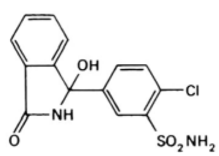
CHLORTALIDONUM

Chlortalidone ǅǎǌǫǐǁǂƀǌǂǀ

$C_{14}H_{11}ClN_2O_4S$ ¦**Molecular formula** ǦƎǺÂƨǟ Ǧ8ƎÔǟ

338.8 ¦**Relative molecular mass** ǦƎƓÊǺǟ ǦƎǺÂƨǟ ǦŸǪÒǟ

¦**Graphic formula** ǦƎǢǺƎƓţǟ Ǧ8ƎÔǟ



¦**Chemical name** ƟəǺƎŧƎÒǟ ǈèƑǟ

2-Chloro-5-(l-hydroxy-3-oxo-1-isoindolinyl)benzenesulfonamide; 2-chloro-5-(2,3-dihydro-1-hydroxy-3-oxo-1*H*-isoindol-1-yl)benzenesulfonamide; CAS Reg. No. 77-36-1.

.ǺƓǺÀǑǩ ǦƜǝǟÀǟ ƇƎȝ şǕ ǦƜǝǟÀǟ ƇƎȝ ÜǺǺÔƞ ȐƎǜǕ şǕ ȐƎǜǕ ƀǿƺǺǣ ǡƺƜÊƞ ¦**Description** ƺòƺǟ

ÜR ȯƺǢǺǮƎţǟ Ž ǟǟşǣ ÜR ȳǿƺƺşǿƺŸÒǟ Ž ƑȘ R ƘǪǰǟ Ž ƑȘ ǒǺţǟ Ž ƎŸŧȝ ǟǟşǣ Ƙȡ ¦**Solubility** ǦƎǢǺǣşǾǟ

.TS (ȯ/ȟ 750~) ȯƺǢǺǮǺɋǟ Ž ȷǺǣşǾǟ ǦƎƜì

.ȯƺǦŸǒ ǿǼƞ ¦**Category** ǦǺǺǟ

.ǺƎƎǅ ǦǑŸ8ƞ ǦǺşǺǵ Ž ȷşǼƎǒǺǩǿƺŸÒǟ ŞǺǵ ƕƶ ¦**Storage** ȸǺÂǺǪǟ

REQUIREMENTS ƘǦǖǁƱǩǆ!ƒ

ȸȝ ǼǺÂǺ ƑȘ %98.0 ȸȝ ǬǾǺ Ƒ Ǻƞ ƻŸȝ ȷşǼƎǒǺǩǿƺŸÒǟ ƀƺǪȜ ¦**General requirement** ȳǺǨǟ ǼŸÛǪţǟ

.ǦǺǺǄţǟ ǥǺţǟ ƃǕ ţƺǅǺǝǺǣ ǦǣƺÊƬ Û $C_{14}H_{11}ClN_2O_4S$ ȸƞ %102.0

¦**Identity tests** ƕǐǌǈǁǀ ǃƐƀǴǏǭƐ

.ǺǨƞ CŞ B ȷǟǿǺǪǹƑǟ ƸǺǺǾ ȷǕ şǕ ǺǨƞ BŞ A ȷǟǿǺǪǹƑǟ ƸǺǺǾ ȷǕ Ǻƞǖ •

ǒǟǺŧƩǟ ƘƠ ǦǨì ǰǟ ǦǑÛǺƞ Ž ƟəƺȐǟ ƺƎÛǟ ǟǺƹ" ȷǟƺǺȝ ƘƠ 8ƺòƺƞ ƺȽ ǺŧǬ ǸƜǺǟ ƻǝǅǾ :A

ƘƠ ǦǨì ǰǟ Ž îǺÔǪƞƑǟ ƺƎù ƸǣǺÛǪ .(43 ǦƜǺÔǟ Û1 ǼŸǑǟ) "Spectrophotometry in the infrared region

.ȷşǼƎǒǺǩǿƺŸÒŸǒ *reference spectrum* ƟǨǅǺţǟ ƺƎÛǟ ȸƞ şǕ RS ȷşǼƎǒǺǩǿƺŸÒǟ ȸƞ ǰǪǺ ƀǾǟ ƺƎÛǟ Ʒƞ ǒǟǺŧƩǟ

ǦɆÊɆəÀöä ǦȞÕǤöä ĘæÀÛǬǩ ."Related substances ǦǒÀÎţä ǻäzţä" ɉäzȺȝ ǨƠ ǨÕģɍ Ȣzòzţä øÀǬǹɍä ÀȚǷä :B
.B òzŸǂä ȸȠ ǰǬǨ ɄøǬä ǦɆÊɆəÀöä ǦȞÕǤöä ȝȠ ǥÆÎöäȿ ÀȚÀţäȿ ȝȩzţä Ž A òzŸǂä ȸȠ ǦΘÀÀöä
Ž ǰÀÂţä üzÆǂ .ÆÀÆì ÀÀòǕ ɉzǒ ǰǨÀ ÜTS (ò/ȟ 1760~) ȭÀøzÀŸÊöä Ȑ þ ȸȠ Ōȡ 1 Ž ȠŸȠ 20 āäØǂ :C
.ɄDzÊÀÀæ ƂǕ Àþǖ ɉzǒ ǰǨÀ ÜR òzǯÀǷ - 1 ȸȠ ȠŸȠ 10 ȢÀȒǂȿ ɄəÀȠ ȳÀþ

ȳzÀǻzÔöä ÆɆÊõȿøÆɆȽ òzŸȚ ȸȠ Ōȡ 10 Ž ȟ 1.0 òzŸȚ ɉzÒÀ :**Solution in alkali** ɃzŸȭöä Ž òzŸǂä
Ȣzòzȡ zȽ Àŧõ ɉøÀȭÀ ÀȠÆȝ Yw2 ɃøÀɆȟţä ɉzŸöä òzŸȚ ɉzǒ ȸȝ ɉzŸöä ǥÆì ÆÀÂǩ ɍȿ ǨɆzÀò TS (ò/ȟ 200~)
.(53 ǦɄÀÔöä Û1 ÆŸǑä) "Colour of liquids ȬəzÊöä ɉzǒ" ɉäzȺȝ ǨƠ

.ȟ/ȠŸȠ 1.0 ȸȝ ÆÀÂÀ ɍ :**Sulfated ash** ǨǍŸÊţä ǻÀȠÀöä

.ȟ/ȠŸȠ 5.0 ȸȠ ÀǯõǕ ÆȭÀÀ ɍ Ü°ȳ 105 ÆȺȝ ǨæÀǯöä ɉàzöä ʔøǬǵ ȤÀDzǂ :**Loss on drying** ȤɆÀDzǬȭÀæ ÆȭÀöä

ǦȭɆȩÀöä ǦȭǤÛöä āäÀÎǬèä" ɉäzȺȝ ǨƠ Ȣzòzȡ zȽ Àŧõ øÀǬǹɍä ĘǨÛǂ :**Related substances** ǦǒÀÎţä ǻäzţä
15 ȸȠ ǰÀÂȠȿ ǦŸȣ8ȡ ǥǻÀŧõ R2 ÀÒɆŸɆÊöä ǦȠƔȽ ȳÆǺǬÊǂȿ (84 ǦɄÀÔöä Û1 ÆŸǑä) "Thin layer chromatography
ǦɄɆÀÔöä ʔŸȝ ɎÔÀÀȠ ĘǨÛǂ .õÀɄǬȡ øzÛõ TS (ò/ȟ 17~) ÀǷzȠǰä òzŸȚ ȸȠ ȳzDzǵ ȝȿ R òzǷÀǩzǣ-1 ȸȠ ÀŧDzǵ
:(B) òzŸǂäȿ Ōȡ 1 Ȭõ Ž øÀǬǹɍä ǥǻÀȠ ȸȠ ȠŸȠ 10 ɃzȜ :(A) òzŸǂä Û R òzǷÀǯɆţä Ž ȬɆÀȚ 3 ȸȠ ÀǬȍȿÀÒȠ 10
2-(4-Chloro-3- ȸȠ ȠŸȠ 0.10 ɃzȜ :(C) òzŸǂäȿ Ōȡ 1 Ȭõ Ž RS ɉȿÆɆÀǩ øzŸÒöä ȸȠ ȠŸȠ 10 ɃzȜ
Ž ȤDzǬö õÀǬǂ Ûāäà Î ǬèɍäǥǨDzǵ ȸȠ ǦɄɆÀÔöä ţÀǷ Æȟæȿ .Ōȡ 1 Ȭõ Ž benzoic acid RS (sulfamobenzoyl
ÛA òzŸǂä ȸȠ ǰǬǨ ǦȞÕæ ǦÀǕ ɉzÒǨ ɍ .(ÀǬȠzǷÀǷ 254) ǦɆDzÊÀÀǤöä àzz ǦȞì ǰä Ž āäÀÎǬèɍä ÙÛƯ ÒɄÀȿ õäzŢä
.C òzŸǂä ȸȠ ǦΘÀÀöä ȭŸǨ ȸȠ ǥÆì ÀǯõǕ ÛǦɆÊɆəÀöä ǦȞÕǤöä õÀǯǬèÀæ

òzŸȚ ǦÛèäzæ ÀÀɆȟȿ R ȸÀÆÀǨǦöä ȸȠ Ōȡ 50 Ž ÛǦɆüzǦȒȠ ǦǷȿàzȡ Ûȟ 0.3 ǦäÀȩ āäØÀ :**Assay** ǦÊÀÀȭţä
ǨƠ Ȣzòzȡ zȽ Àŧõ ÆȤǯä âÀɆȭȠ ǦÀȤÀöä ǦÛȭǷ ƙȟǩȿ ÛVS (ò/òzȡ 0.1) ȳzǷzȠǰä ȬɆǩzæ ɄȝÀæø ÆɆÊõȿøÆɆȽ
ȸȠ Ōȡ 1 Ȭõ .(142 ǦɄÀÔöä Û1 ÆŸǑä) B ǦȭÀÀÛöä Û"Non-aqueous titration ɄəÀȠŸöä Ùèzöä Ž ǥÀÀɆȟţä" ɉäzȺȝ
.$C_{14}H_{11}ClN_2O_4S$ ȸȠ ȠŸȠ 33.88 ùzÀÒÀ VS (ò/òzȡ 0.1) ȳzǷzȠǰä ȬɆǩzæ ɄȝÀæø ÆɆÊõȿøÆɆȽ òzŸȚ

øøøøø

CLOXACILLINUM NATRICUM

Cloxacillin sodium !ǊĭǬǊȚǁǁ ǄĭǂĭƸƪƪǁǊǂǁ

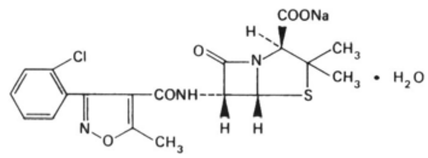
Cloxacillin sodium (non-injectable ǄƽΘǂǁ üǤƽǁǁ þĭȝ !ǊĭǬǊȚǁǁ ǄĭǂĭƪƪǁǊǂǁ

Cloxacillin sodium, sterile !ĭƽƴǁǁ Û!ǊĭǬǊȚǁǁ ǄĭǂĭƪƪǁǊǂǁ

$C_{19}H_{17}ClN_3NaO_5S, H_2O$:**Molecular formula** [illegible]

475.9 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Sodium (2*S*,5*R*,6*R*)-6-[3-(*o*-chlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; sodium [2*S*-(2α,5α,6β)]-6-[[[3-(2-chlorophenyl)-5 methyl-4-isoxazolyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylate monohydrate; monosodium [3-(*o*-chlorophenyl)-5-methyl-4-isoxazolyl]penicillin monohydrate; CAS Reg. No. 7081-44-9.

[illegible] :**Description** [illegible]

[illegible] 500 [illegible] TS [illegible] 750~) [illegible] 30 [illegible] 2.5 [illegible] :**Solubility** [illegible]

[illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] 25 [illegible]

[illegible] :**Labelling** [illegible]

[illegible]

[illegible] :**Additional information** [illegible]

[illegible]

[illegible] %90.0 [illegible] :**General requirement** [illegible]

[illegible] $C_{19}H_{18}ClN_3O_5S$ [illegible]

:**Identity tests** [illegible]

- [illegible] B [illegible] A [illegible]

[illegible] :A

[illegible] .(43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region

reference spectrum [illegible] RS [illegible]

[illegible]

[illegible] 2 [illegible] R [illegible] chromotropate [illegible] 2 [illegible] 2 [illegible] :B

.TS [illegible] 1760~) [illegible]

[illegible] 4-3 [illegible] 150 [illegible]

[illegible] B [illegible] .TS [illegible] 60~) [illegible] 20 [illegible] :C

[illegible] 1 [illegible]) [illegible] "General identification tests [illegible]

.(123

[illegible] 10 [illegible] :**Specific optical rotation** [illegible]

$[a]_{D}^{20\,°C} = +163 + 172°$ [illegible]

Determination of water by [illegible] :**Water** [illegible]

[illegible] 0.25 [illegible] (145 [illegible] 1 [illegible]) A [illegible] "Karl Fischer method

[illegible] 45 [illegible] 35 [illegible]

5.0 - [illegible] 0.10 [illegible] :**pH value** [illegible]

.7.0

Oxygen flask [illegible] :**Chlorine** [illegible]

[illegible] 20 [illegible] 0.040 [illegible] (132 [illegible] 1 [illegible]) "method

[illegible] VS [illegible] 1) [illegible]

[illegible] 20 [illegible] 2.5 TS [illegible] 130~) [illegible] 2.5 [illegible]

VS [illegible] 0.01) [illegible] VS [illegible] 0.01) [illegible]

[illegible] ferric ammonium sulfate TS [illegible] 45) [illegible]

[illegible] C1 [illegible] 0.3546 [illegible] VS [illegible] 0.01) [illegible] 1 [illegible]

[illegible] 75-70 [illegible]

[illegible] 1000 [illegible] 50 [illegible] :**Assay** [illegible]

[illegible] 2.0 [illegible]

°ÿ 60 ÆÂ3 ƟǝÅƞ ÿÅþ Ž 3ȑ ɀÅş āɀǤǫǰä ÆÊł Û ǯÂŧł ÛTS ĘǤəÂöä ÆÅǿɀŶõ/ȯşäÅÆƐqä ȯɀŶƮ ȸƞ Ōƞ 10 ƙäɀǤǫǰä
.(A ȯɀŶǂä) °ÿ 20 БÛ Ğ3ÅÊǣ āɀǤǫǰä åÅÅł .ÅƞÅǪ ĞŌƐęå 25 ġÆƞ
.(B ȯɀŶǂä) ǯÂŧłş ŏÅţä ȸƞ Ōƞ 10.0 ƟǿǫÅǯöä āɀǤǫǰä БÛ ȣÅŘł
ȸɀƠ ÆÅǾƞ ĞƐŶǹ ŌǣÅŌƞ ÅǪƞɀǫÅǫ 343 ĞäÅȩ ƟŧƮ3Û ĞDZɀƞ ȯɀü ÆÂ3 ǈè 1 ĞǫÅǺǣ ĞŌĞü î ÅǪ âÅŌł ŌƐDZüǩ ȷşÆǣş
.B ȯɀŶǂä ŌDZǰ ŏÅţäş A ȯɀŶǂä ŌDZǰ TS ĘǤəÂöä ÆÅǿɀŶõ/ȯşäÅÆƐqä ȯɀŶƮ ȸƞ Ōƞ 10ş ŏÅţä ȸƞ Ōƞ 2.0 ȸƞ ÅƶÂƞ
ĞǫǿÅŌţÅǣ B ȯɀŶǂä ņî ÅǪş A ȯɀŶǂä ņî ÅǪ ƙǣ ȧÅÅöä ȸƞ ÅŁǿÅǪǹä åäÅţä ġåÅţä Ž $C_{19}H_{18}ClN_3O_5S$ ǿäÆŌƞ ÆÊȞł
âÅƐŌƞ Ž ƟȞDZÅţä ȯɀŶǂä î ÅǪ ȷɀȮÅ ȷÛ Æƶ .ȸƞäÅǪöÅǣş ĞŏÅÎţÅǣ îɀȞÅţä RS ÿɀÅåɀÔöä ƙÅƐèÅÊõɀŶõ 3ƞ
.0.02 ± 0.4 ȡȣÅõ ŌȮÎǣ ÅƐƐţä ƟəɀŘöä ƵƐÛöä

!ĭŝy/Ⅱ !NjĭǫNjƬⅡ DžĭĦĭƨƑƨ lNjŧl üƜǓ ƕĭƺƑƮƌ lƑǤŧƯƗDž
Additional Requirements for Sterile Cloxacillin Sodium

"Sterility testing of antibiotics ĞÅɀƐΣä ğäåÅŘŧŶö ĞƞÅŌȞöä ǿÅǪǹä" Ž åǿş Åţ ÆƐDZǪÊǩ ¦**Sterility** ĞƞÅŌȞöä
ǿÅǪǹɍä ğäöäÅDZÛ şÛ TS äÅÅƐŶÊÅǤöä ĞɀÅȑÛ 3ƞ ŏÅÎȣÅǣ ǴƐïÅǪöä ǿÅǪǹä ğäöäÅDZÛ ÅƞÛ ĘƐǤÛǪǣ Û(162 ĞȞÅÔöä Û1 ÆŶÕä)
.ÅïÅǤţä

!ĭŝy/Ⅱ üƑDžyŧƨǘⅡ ǭyɃŽⅡ !NjĭǫNjƬⅡ DžĭĦĭƨƑƨ lNjŧl üƜǓ ƕĭƺƑƮƌ lƑǤŧƯƗDž

Additional requirements for Cloxacillin sodium for sterile use

Test for sterility of non-injectable ȸŌȞŶö ĞŶǣÅŌöä Ƙɗ ğäÅŘȞǪÊţä ĞƞÅŌ3 ŌDZǰ ǿÅǪǹɍä" БÛ ÆƐDZǪÊÅ
.(ĞÅÅƐƱqä ĞȞĞÛöä Ž 32 ĞȞÅÔöä Û5 ÆŶÕä) "preparations

ǿÅǪǹɍä" ȷäɀÂ3 ǨƠ ȣɀȍɀƞ ɀȽ Åŧõ ǿÅǪǹɍä ĘǥÛł ¦**Bacterial endotoxins** ĞƐƞɀǫÅƨä ĞƐŶǹäÆöä ğÅǫÅÅǾöä
ɍ Û(ĞÅÅƐƱqä ĞȞĞÛöä Ž 30 ĞȞÅÔöä Û5 ÆŶÕä) "Test for bacterial endotoxins ĞƐƞɀǫÅƨä ĞƐŶǹäÆöä ğÅǫÅÅǾöä ŌDZǰ
.ƞŶƞ 1 Ōõ Ž RS ƟŶǹäÆöä ȷÅÅǾöä ȸƞ ĞƐşå ġÆģş 40 ȸƞ ÅǯõÛ ȸɀȜ

ǾǾǾǾǾ

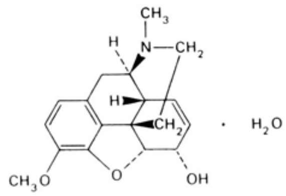
CODEINUM MONOHYDRICUM

Codeine monohydrate DžĭǫNjⅡ lƐþǫĭǉ ăǫƑƟǽ

$C_{18}H_{21}NO_3, H_2O$ ¦**Molecular formula** ĞƐÅÂƨä ĞȣƐÔöä

317.4 ¦**Relative molecular mass** ĞƐĞÊÅöä ĞƐÅÂƨä ĞŶǪÕöä

Graphic formula



Chemical name

7,8-Didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol monohydrate; CAS Reg. No. 6059-47-8.

Description

Solubility … (~750) g/l TS … R.

Category

Storage

Additional information

REQUIREMENTS

General requirement … 99.0% … 101.0% … $C_{18}H_{21}NO_3$ …

Identity tests

A. … 5 … 1 … (~1760 g/l) TS … 1 … 1 … (25 g/l) TS … (~130 g/l) TS.

B. … 1 … 0.5 … Selenious acid/… TS …

C. … 156 °C.

Specific optical rotation … 20 mg/ml … (~750 g/l) TS …; $[a]_D^{20\,°C} = -142$ to $-146°$.

ĂĿźÀö ǒÀţä ȸŋ Ōŋ 10 Ž ȟ 0.050 ÂĿõÀǪæ ȯźŸǂä ȷźȮÀ :**Clarity and colour of solution** ȯźŸǂä ȷźǿş ǒÀÀö .ȷźŸöä ČÆȝş

.ȟ/ŋŸŋ 1.0 ȸȝ ÆÀÂÀ ɍ :**Sulfated ash** ǨÀŸÊţä ắÀŋÀöä

ɍş ȟ/ŋŸŋ 50 ȸŋ Ōęǚ ÆŌÀÀ ɍ Ü°ÿ 105 ÆÀȝ ǨæÀǯöä ȷäźöä ʔøǪǵ ȤâDzł :**Loss on drying** ȤĿÀDzǪōÀæ ÆŌÀöä .ȟ/ŋŸŋ 60 ȸŋ ÀǯõǗ

ɍ Àŋ R ȷźæÀÒöä ÆĿÊõǗ ɄəÀǻ ȸŋ ɃÀȠä ǒÀţä Ž Ōŋ/ŋŸŋ 5.0 ÂĿõÀǪæ ȯźŸȚ ǒÀĿÀæ ŋŸǤÀ :**pH value** ǒÀĿÀǤöä ǦŧĿę .9.0 ȸȝ ŌŌÀ

ǦŌĿęÀöä ǦŌǤÛöä āäÀÎǪèä" ȷäźÀȝ ǨƠ ȣźòźŋ źĿ Àŧõ øÀǤǪǹɍä ĘǭÛł :**Related alkaloids** ǦòÀÎţä ǧÀĿǭäźŸŌöä 72 ȸŋ ǰÀÂŋş ǦŸǯȣŋ ǥåÀŧõ R1 ÀÒĿŸĿÊöä ǦŋƳĿ ÿÆÅǪÊłş (84 ǦĦÀÔöä Û1 ÆŸǑä) "Thin-layer chromatography 260~) ÀĿǭźŋɉä ȯźŸȚ ȸŋ ÿźDzǵ 6ş R ȷÀÊÒĿźŸÒĿÊöä ȸŋ ÀŧDzǵ 30ş TS (ȯ/ȟ 750~) ȯźǭÀǯÀɊä ȸŋ ÀŧDzǵ ȸŋ ÿźDzǵ 4 ȸŋ ǰÀÂŋ Ž ƙÀǭä ƙȯźŸȚ ȸŋ ÀǪǿşÀÒŋ 10 ǦĦĿÀÔöä ʔŸȝ ÀŸÔÀÀŋ ĘǭÛł .õÀĦǪŋ øźÛõ TS (ȯ/ȟ ȸŋ ŋŸŋ 50 ɃźȜ :(A) ȯźŸǂä ÛTS (ȯ/ȟ 750) ȯźǭÀǯÀɊä ȸŋ ÀŧDzǵ 1ş VS (ȯ/ȯźŋ 0.01) ÕÀøźŸõşøÆĿTä Ȑƥ ȸŋ ǦĦĿÀÔöä ţÂǭ ÆĦæş .Ōŋ 1 Ōõ Ž øÀǤǪǹɍä ǥåÀŋ ȸŋ ŋŸŋ 0.66 ɃźȜ :(B) ȯźŸǂäş Ōŋ 1 Ōõ Ž øÀǤǪǹɍä ǥåÀŋ ÙÛƯ ÒĦÀłş TS2 ÿźĿèÀǩźǤöä ǧÀǭźŋÂæşåźÀǗ ȯźŸȚ ǦÛèäźæ æÀÀł ÛöäźTä Ž ȤDzǪō õÀǪł Ûāäà ÎǪèɍä ǥƘDzǵ ǦΘÀÀöä ÕŸǨ ȸŋ ǥÆì ÀǯõǗ ÛǦĿÊĿəÀöä ǦĦŌǤöä ǒÀǻǪèÀæ ÛA ȯźŸǂä ȸŋ ǰǪǨ ǦĦŌæ ǦÀǗ ȷźȮǨ ɍ .øÀȚÀöä ǒźȑ Ž āäÀÎǪèɍä .B ȯźŸǂä ȸŋ

10 ȣÀȒłş R1 ɄDzŸǯöä ÕĿǪĿèɉä Ȑƥ ȸŋ Ōŋ 30 Ž ÛǦĿùźǤȒŋ ǦǭşäźŋÛȟ 0.25 ǦäæÀę āäØÀ :**Assay** ǦÊÀÀŌţä ǨƠ ȣźòźŋ źĿ Àŧõ VS (ȯ/ȯźŋ 0.1) ÕÀøźŸõƘǤöä Ȑƥ ȯźŸȚ ǦÛèäźæ ÀÀĦłş R ÕĿǪĿèɉä ÆÀøÆĿŒǗ ȸŋ Ōŋ ȸŋ Ōŋ 1 Ōõ .(142 ǦĦÀÔöä Û1 ÆŸǑä) A ǦŌÀÛöä Û"Non-aqueous titration ɄəÀŋŸöä Ùèźöä Ž ǥÀÀĦţä" ȷäźÀȝ .$C_{18}H_{21}NO_3$ ȸŋ ŋŸŋ 29.94 ùźÀÒÀ VS (ȯ/ȯźŋ 0.1) ÕÀøźŸõƘǤöä Ȑƥ ȯźŸȚ

ØØØØØ

CODEINI PHOSPHAS

Codeine phosphate DzĭǫŊǀǁɛ ǀƑƻƾ

hemihydrate ǀɛƥǫĭǋǁɛ ƹTǳ DzĭǫŊǀǁɛ ǀƑƻƸ

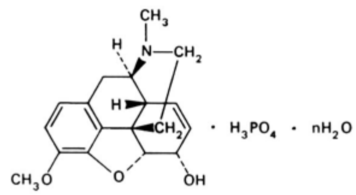
Sesquihydrate ǀɛƥǫĭǋǁɛ ƹTǳŊ ƕĭǫƑΘĆ DzĭǫŊǀǁɛ ǀƑƻƾ

$C_{18}H_{21}NO_3$, Ü(ǧäøÆĿTä ȤÔǭ) Û$C_{18}H_{21}NO_3$, H_3PO_4, ½H_2O :**Molecular formula** ǦĿÀÂƨä ǦȣĿÔöä

.(ğøÆŀŢã ȤÔǾş ǦΛấİġǚ) ÛH_3PO_4, 1½H_2O

ȤÔǾş ǦΛấİġǚ) 424.4 Ü(ğãøÆŀŢã ȤÔǾ) 406.4 ؛**Relative molecular mass** ǦƐĢÊΛöã ǦƐÅΛÂƨã ǦŸǪÒöã
.(ğãøÆŀŢã

؛**Graphic formula** ǦƐǾÅƐǤţã Ǧ8ƐÔöã



n = ½ (hemihydrate)

n = 1½ (sesquihydrate)

؛**Chemical name** ȖəÅƐŧƐÒöã ǀèɼã

7,8-Didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol phosphate (1:1) (salt) hemihydrate; CAS Reg. No. 41444-62-6 (hemihydrate). 7,8-Didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol phosphate (1:1) (salt) sesquihydrate; CAS Reg. No.5913-76-8 (sesquihydrate).

.ǦȞəãÀöã ƇÆȝ ÜȒƐæǚ ƁøȤǩæ ȧȤȞÊƞ şǚ ǥƘ8ö ȷȤŸöã ǦƩÆȝ ğãøȤŸæ ؛**Description** Ȥòȥöã

ãäşæ Ƙȡ ÜTS (ȯ/ȟ750~) ȯȤǾÅǮΛɋã Ž ȷÅæşØöã ǴƐȞì ÜöÅţã ȸȠ öãÂDZǚ 4 Ž ãäşæ ؛**Solubility** ǦƐǾÅæşØöã
.R Ƙǫɉã Ž ɼş R ÿøȤȥşøȤŸÒöã Ž ÅƐŸŧȝ

.ȸǾÒÊɦ ÜòÅǺÊŸö ấÅȒȠ ؛**Category** ǦÅΛöã

.öȤȒöã ȸȠ ǦƐŧȚ Û ÿÅÒǵǚæ ǦÕŸ8ȠǦΛşÅǵ Ž ȸΛấȤÒöã ğÅΛÊȤ ȘÅǵ Ɑƶ ؛**Storage** ȸΛÂǺǪöã

şǚ ğãøÆŀŁ ȤÔǾ ȸΛấȤÒöã ğÅΛÊȤ ƘǾÅõ ãæǚ ÅŧƐȥ ǦΛşÅΣã ɁŸȝ ǦƐŧÊǪöã ȡæÅÒǾ ȷǚ Ɑƶ ؛**Labelling** ǀƐèȤǪöã
.ğãøÆŀŢã ȤÔǾş ǦΛấİġǚ

.8Åƨã öãȤŢã Ž ȸΛấȤÒöã ğÅΛÊȤ ÀŁÂǪǩ ؛**Additional information** ǦƐȤÅȓǚ ğÅȠȤŸǶȠ

REQUIREMENTS ƘǦǚǚƱƘǆž!ƒ

ȸȝ ÆΛÂΛ ɼş %98.0 ȸȝ ÕÕΛ ɼ Åȡ ɁŸȝ ȸΛấȤÒöã ğÅΛÊȤ ƁȤǪƠ ؛**General requirement** ÿÅǶöã ÆŸǕǪţã
.ǦÅÅDZȤţã ġấÅţã ƂǚţȤDZÀöÅæ ǦæȤÊŢ Û$C_{18}H_{21}NO_3$, H_3PO_4 ȸȠ %101.0

:**Identity tests** [illegible]

[illegible] 1 [illegible] TS ([illegible] 1760~) [illegible] 1 [illegible] 5 [illegible] :A

[illegible] 1 [illegible] TS ([illegible] 25) [illegible]

.TS ([illegible] 130~) [illegible]

[illegible] TS [illegible] /selenious acid [illegible] 0.5 [illegible] 1 [illegible] :B

[illegible] - [illegible]

[illegible] B [illegible] TS ([illegible] 100~) [illegible] 20 [illegible] :C

[illegible] "General identification tests [illegible]"

.(122 [illegible]

[illegible] TS ([illegible] 100~) [illegible] 1 [illegible] 0.2 [illegible] 5 [illegible] :D

.°[illegible] 105 [illegible] TS ([illegible] 750~) [illegible]

.([illegible]) °[illegible] 156 [illegible]

[illegible] 20 [illegible] :**Specific optical rotation** [illegible]

. $[a]_D^{20\,°C} = -98$ to $-120°$ [illegible]

20[illegible] TS ([illegible] 130~) [illegible] 2 [illegible] 0.70 [illegible] :**Chlorides** [illegible]

Limit test for [illegible]

.[illegible] 0.35 [illegible] (124 [illegible] 1 [illegible]) "chlorides

[illegible] 20 [illegible] 0.50 [illegible] :**Sulfates** [illegible]

.[illegible] 1 [illegible] (125 [illegible] 1 [illegible]) "Limit test for sulfates [illegible]

[illegible] 10 [illegible] 0.40 [illegible] :**Clarity and colour of solution** [illegible]

[illegible] Yw2 [illegible]

.(53 [illegible] 1 [illegible]) "Colour of liquids

[illegible] :°[illegible] 105 [illegible] :**Loss on drying** [illegible]

[illegible] 50 [illegible] 30 [illegible]

.[illegible] 70

.5.0 - 4.2 [illegible] 0.04 [illegible] :**pH value** [illegible]

ǦŎǂɕǺöä ǦŎǤÛöä āäÀÎỌèä" ɉäɀȜȝ ǨƠ ȣȥòɀŋ ɀȽ ǺɫȭŐ øǺǤŎǹɍä ĘǸÛł ¦**Related alkaloids** ǦŏǺÎţä ğǺɆɸäɀŸǑöä 72 ȸŋ ǰǺÂŋş ǦŸȣȢ ǥǻɫȭ R1 ǺÒĦŸĦÊöä ǦŋɎȽ ÿÆǺÊǺş .(84 ǦĦǺÔöä Û1 ÆŸŎä) "Thin layer chromaatography 260~) ǺɆɀŋɟä ȯɀŸȚ ȸŋ ÿɀǲǵ 6ş R ɉǺÊÒȽɀŸÒĦÊöä ȸŋ ǺɫǲǶ 30ş TS (ȯ/ȟ 750~) ȯɀɸǺȜǺɋä ȸŋ ǺɫǲǶ ȸŋ ÿɀǲǵ 4 ȸŋ ǰǺÂŋ Ž ƙǺɸä ƙȯɀŸȚ ȸŋ ǺɸşǺÒŋ 10 ǦĦǺÔöä ɁŸȝ ŸÔǺǺŋ ĘǸÛł .ȭǺĦɸŋ øɀÛȭ TS (ȯ/ȟ ȸŋ ŋŸŋ 50 ȻɀȜ :(A) ȯɀŸɨä Û(ȯ/ȟ 750~) ȯɀɸǺȜǺɋä ȸŋ ǺɫǲǶ 1ş VS (ȯ/ȯɀŋ 0.01) ȬǺøɀŸȭşøÆĦTä ȐȸŽ ȸŋ ǦĦǺÔöä ţÂɸ ÆĦǺş .Ōŋ 1 Ōȭ Ž øǺǤŎǹɍä ǥǺǺŋ ȸŋ ŋŸŋ 0.66 ȻɀȜ :(B) ȯɀŸɨäş Ōŋ 1 Ōȭ Ž øǺǤŎǹɍä ǥǺǺŋ ÙÛƯ ÒĦǺǺş TS2 ÿɀĦèǺǨɀǦöä ğǺɸɀŋÂǺ şǻɀǺÛ ȯɀŸȚ ǦÛèäɀǺ ǽǺǺ ÛöäɀTä Ž ȤǲɸȰ ȭǺɸǨ Ûāä ÀÎỌèɍä ǥKǲǶ ǦӨǺǺöä ȬŸǨ ȸŋ ǥÆì ǺȜȭÛ ÛǦĦÊĦǺöä ǦǨŎǦöä ŏǺǺȜèǺǺ ÛA ȯɀŸɨä ȸŋ ǰɸǺǨ ǦǨŎǺ ǦǺÛ ɉɀȮǨ ɍ .øǺȚǺöä ŏɀȉ Ž āäÀÎỌèɍä .B ȯɀŸɨä ȸŋ

ǺǺǺĦǺş R1 ɄǲŸȜöä ȬĦɸĦèɟä ȐȸŽ ȸŋ Ōŋ 30 Ž ÛĦĦùɀǦȒŋ Ǧɸşäɀŋ Ûȟ 0.35 ǦǺäǺɕ āäØł ¦**Assay** ǦÊǺǺŎţä ɄǝǺŋŸöä Ùèɀöä Ž ǥǺǺǺĦţä" ɉäɀȜȝ ǨƠ ȣȥòɀŋ ɀȽ ǺɫȭŐ VS (ȯ/ȯɀŋ 0.1) ȬǺøɀŸȭƘǦöä ȐȸŽ ȯɀŸȚ ǦÛèäɀǺ 0.1) ȬǺøɀŸȭƘǦöä ȐȸŽ ȯɀŸȚ ȸŋ Ōŋ 1 Ōȭ .(142 ǦĦǺÔöä Û1 ÆŸŎä) A ǦŎǺǺÛöä Û"Non-aqueous titration .$C_{18}H_{21}NO_3, H_3PO_4$ ȸŋ ŋŸŋ 39.74 ùɀǺÒǺ VS (ȯ/ȯɀŋ

ØØØØØ

COFFEINUM

Caffeine ǲɨɨȝFǀǁƐ

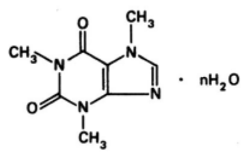
Caffeine anhydrous ǏəFǲǘǁƐ ǲɨɨȝFǀǁƐ

Caffeine monohydrate ǀƐþɸɨǋǁƐ ǎɸFӨƈ ǲɨɨȝFǀǁƐ

.(ğäøÆĦTä ȻǻǺǵÛ) $C_8H_{10}N_4O_2, H_2O$ Û(ɄǝǺŋŸöä) $C_8H_{10}N_4O_2$ ¦**Molecular formula** ǦĦǺǺÂȤä ǦȣĦÔöä

.(ğäøÆĦTä ȻǻǺǵÛ) 212.2Û(ɄǝǺŋŸöä) 194.2 ¦**Relative molecular mass** ǦĦǦÊǺöä ǦĦǺǺÂȤä ǦŸɸÒöä

¦**Graphic formula** ǦĦɸǺĦǤţä ǦȣĦÔöä



n = 0 (anhydrous)
n = 1 (monohydrate)

Chemical name:

3,7-Dihydro-1,3,7-trimethyl-1*H*-purine-2,6-dione; CAS Reg. No. 58-08-2 (anhydrous). 3,7-Dihydro-1,3,7-trimethyl-1*H*-purine-2,6-dione monohydrate; CAS Reg. No. 5743-12-4 (monohydrate).

Description:

Solubility: 60 ... 100 ... (~750) TS ... R.

Category:

Storage:

Labelling:

Additional information:

REQUIREMENTS

General requirement: 98.0% ... 101.0% ... $C_8H_{10}N_4O_2$ ...

Identity tests:

• A ... B ... C ... D ...

A: ... "Spectrophotometry in the infrared region" (43 ...) ... 80 °C ... RS ... *reference spectrum*.

B: ... 10 ... 1 ... (~250) TS ... 0.5 ... (~60) TS ... 1 ... (~100) TS ... 3-2 ... (~80) TS.

C: ... (~70) TS ...

.TS (ȯ/ȟ 80~) ÿζłắζÔǿǟ

.°ÿ 236 ǦǟǟÀę Û°ÿ 80 ÆÅȝ ȤĿÅDzǪǿǟ ÆĦǣ øÅŢÔφɏǟ ģøǟÀǵ ǦDZøǻ ȠŸǦǩ :D

ÅĿζÅȍ ƃÅȣǿǟ ŏÅţǟ ȡȠ Ōȡ 10 Ž ȟ 0.50 ȯζŸȚ ȷζȮł ¦**Clarity and colour of solution** ȯζŸǂǟ ȷζōȘ ŏÅÅȍ

.ȷζŸǿǟ ƇÆȝȘ

.ȟ/ȠŸȠ 1.0 ȡȝ ÆłÂł ɏ ¦**Sulfated ash** ǨÅŸÊţǟ ǻÅȠÀǿǟ

ÀǰõǕ (ƟǝÅȠƳǿǟ) ƙĿζÅȮǿǟ ÆŌÅł ɏ Û°ÿ 80 ÆÅȝ ǨǟÅǰǿǟ ȷàζǿǟ ɁøǪǵ ȤÅDzł ¦**Loss on drying** ȤĿÅDzǪǿÅǣ ÆŌÅȯǿǟ

.ȟ/ȠŸȠ 90 ȡȠ ÀǰõǕ ɏȘ ȟ/ȠŸȠ 50 ȡȠ ŌęǕ ğǟøÆĿŢǟ ɃǻÅģǕ ƙĿζÅȮǿǟ ÆŌÅł ɏ .ȟ/ȠŸȠ 5.0 ȡȠ

.6.6-4.8 ÛR ȷζǟÀȮǿǟ ÆĿÊõǕ ƟǝÅÅǪ ȡȠ ƃÅȠǟ ŏÅţǟ Ž Ōȡ/ȠŸȠ 10 ÂĿõÀǪǣ ȯζŸȚ ŏÅŁÅǣ ȠŸǦł ¦**pH value** ŏÅŁÅǦǿǟ ǦȶĿę

ǦŌĿęÀǿǟ ǦōǦÛǿǟ ǟǟÀÎǪèǟ" ȷǟζłȝ ǨƠ ȣζòζȠ ζȽ ÅȶõøÅǦǪǹɏǟ ĘĿǦÛł ¦**Related substances** ǦŏÅÎţǟ ǻǟζţǟ

4 ȡȠ ǰłÂȠȘ ǦŸǦƁȟ ģǻÅȶõ R2 ÅȮĿŸĿÊǿǟ ǦȠƳŁ ÿÆǺǪÊǨȘ Û(84 ǦĦÅÔǿǟ Û1 ÆŸŎǟ) "Thin-layer chromatography

øζÛõ TS (ȯ/ȟ 260~) ÅĿφζȠɉǟ ȯζŸȚ ȡȠ ÅȶDzǵ 1Ș R ÿøζζȘøζŸȮǿǟ ȡȠ ÿζDzǵ 3Ș R ȯζφÅǩζǣ-1 ȡȠ ÿζDzǵ

ɃζȜ :(A) ȯζŸǂǟ ÛR ȯζφÅǰĿţǟ ȡȠ ÿζDzǵ 4Ș R ÿøζζȘøζŸȮǿǟ ȡȠ ÿζDzǵ 6 ȡȠ ǰłÂȠ Ž ȯζŸȚ 2 ÀȒĦł .ōÀĦǪȠ

ŸÔÅȠ ĘĿÛł .Ōȡ 1 Ōõ Ž øÅǦǪǹɏǟ ģǻÅȠ ȡȠ ȠŸȠ 0.20 ɃζȜ :(B) ȯζŸǂǟȘ Ōȡ 1 Ōõ Ž øÅǦǪǹɏǟ ģǻÅȠ ȡȠ ȠŸȠ 20

ÛǟǟÀÎǪèɏǟ ģǨDzǵ ȡȠ ǦĦĿÅÔǿǟ ţÂφ ÆĦǣȘ .B ȯζŸǂǟ ȡȠ ÀǪõȘÀȮȠ 5Ș A ȯζŸǂǟ ȡȠ ÀǪõȘÀȮȠ 10 ǦĦĿÅÔǿǟ ɁŸȝ

ǰǪÅǩ ǦĦōǣ ǦÅǕ ȷζȮǩ ɏ .(ÀǪȠζφÅφ 254) ǦĿDzÊÅÅǦǿǟ ȧζζ ǦĦǙɉǟ Ž ǟǟÀÎǪèɏǟ ÙÛƯ ÒĦÅłȘ ŏǟζŢǟ Ž ȤDzǪō ōÀǪł

.B ȯζŸǂǟ ȡȠ ǦƟÅÅǿǟ ŌŸǩ ȡȠ ģÆǙ ÀǰõǕ ÛǦĿÊĿǝÀǿǟ ǦĦōǦǿǟ ŏÅǰǪèÅǣ ÛA ȯζŸǂǟ ȡȠ

ȡȠ Ōȡ 20Ș R ŌĿǪèɉǟ ÆłøÆĿŒǕ ȡȠ Ōȡ 10 Ž ÛǦĿùζǦȒȠ Ǧφȿàζȡ Ûȟ 0.18 ǦǟǟÀę ǟǟØł ¦**Assay** ǦÊłÅŌţǟ

Ž ģÀłÅĦţǟ" ȷǟζłȝ ǨƠ ȣζòζȠ ζȽ Åȶõ VS (ȯ/ȯζȠ 0.1) ŌłøζŸōƘǦǿǟ Ȑþ ȯζŸȚ ǦÛèǟζǣ ÀłÅĦłȘ ȡłζȯζǪǿǟ

Ȑþ ȯζŸȚ ȡȠ Ōȡ 1 Ōõ .(142 ǦĦÅÔǿǟ Û1 ÆŸŎǟ) A ǦŌłÀÛǿǟ Û"Non-aqueous titration ƟǝÅȠƳǿǟ ÙèζǿǟÜ

.$C_8H_{10}N_4O_2$ ȡȠ ȠŸȠ 19.42 ùζÅȮł VS (ȯ/ȯζȠ 0.1) ŌłøζŸōƘǦǿǟ

øøøøø

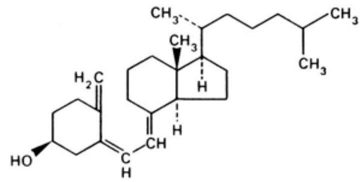
COLECALCIFEROLUM

Colecalciferol üŇǰþĭžĭƨǁƑǀĭǁŇǀ

$C_{27}H_{44}O$ ¦**Molecular formula** ǦĿÅłÂƨǟ ǦȣĿÔǿǟ

384.7 ¦**Relative molecular mass** ǦĿǦÊłǿǟ ǦĿÅłÂƨǟ ǦŸǪȮǿǟ

Graphic formula [illegible]:



Chemical name [illegible]:

(5Z,7E)-9,10-Secocholesta-5,7,10(19)-trien-3β-ol; CAS Reg. No. 67-97-0.

Other name [illegible]: [illegible] Cholecalciferol

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750 [illegible]) TS [illegible] R [illegible] R.

Category [illegible]: [illegible].

Storage [illegible]: [illegible].

Additional information [illegible]: [illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] %95.0 [illegible] %105.0 [illegible] $C_{27}H_{44}O$.

Identity tests [illegible]:

- [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

[illegible] TS [illegible] 4 [illegible] R [illegible] 1 [illegible] 1 [illegible] :B
.[illegible]

[illegible] 0.1 [illegible] R [illegible] 0.3 [illegible] R [illegible] 5 [illegible] 5 [illegible] :C
[illegible] TS (~1760 [illegible]) [illegible]
.[illegible]

[illegible] 10 [illegible] **Specific optical rotation** [illegible]
. $[a]_D^{20\ °C} = +105$ to $+112°$ TS (~750 [illegible]) [illegible]

TS (~750 [illegible]) [illegible] 2 [illegible] 0.04 [illegible] **7-Dehydrocholesterol** [illegible] 7
[illegible] digitonin TS [illegible] 1 [illegible]
.[illegible] 12 [illegible]

[illegible] 20 [illegible] **Assay** [illegible]
[illegible] 100 [illegible] 5.0 [illegible] 100 [illegible] TS (~750 [illegible]) [illegible]
[illegible] 1 [illegible]
[illegible] RS [illegible] $C_{27}H_{44}O$ [illegible] 265
.0.03 ± 0.48 [illegible]

ØØØØØ

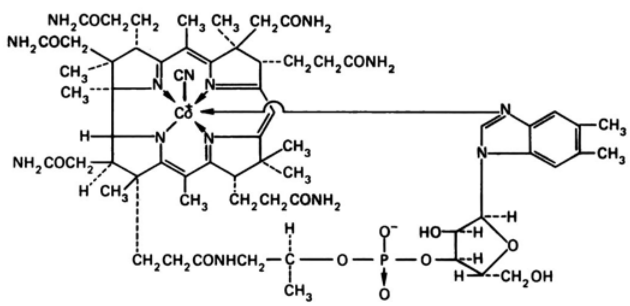
CYANOCOBALAMINUM

Cyanocobalamin [illegible]

$C_{63}H_{88}CoN_{14}O_{14}P$:**Molecular formula** [illegible]

1355 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



Chemical name: [illegible]

α-(5,6-Dimethylbenzimidazol-2-yl)cobamide cyanide; CAS Reg. No. 68-19-9.

Other name: [illegible] B_{12}.

Description: [illegible]

Solubility: [illegible] 80 [illegible] (~750 [illegible]) [illegible] R [illegible] R [illegible] R.

Category: [illegible]

Storage: [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 96.0% [illegible] 102.0% [illegible] $C_{63}H_{88}CoN_{14}O_{14}P$ [illegible]

Identity tests: [illegible]

A: [illegible] 20 [illegible] 230 [illegible] 600 [illegible] 3 [illegible] 278 [illegible] 361 [illegible] 550 [illegible] 1 [illegible] 361 [illegible] 278 [illegible] 1.70 [illegible] 1.90 [illegible] 361 [illegible] 550 [illegible] 3.15 [illegible] 3.45.

B: [illegible] 1 [illegible] 10 [illegible] R [illegible] 2 [illegible] (~100 [illegible]) TS [illegible] 1 [illegible] TS [illegible] 3 [illegible] 0.5 [illegible] (~80 [illegible]) TS [illegible] 0.5 [illegible] R [illegible] 0.5 [illegible] (~60 [illegible]) TS [illegible] 0.5 1-nitroso-2-naphthol-3,6-disodium disulfonate (2 [illegible]) TS [illegible] 0.5 [illegible] (~250 [illegible]) TS [illegible] 1 [illegible]

Clarity of solution: [illegible] 20 [illegible] 10 [illegible]

[illegible] 105 [illegible] **Loss on drying** [illegible] 0.6 [illegible] 5 [illegible] 120 [illegible].

[illegible] **Pseudocyanocobalamin** [illegible] 1 [illegible] 20 [illegible] R [illegible] R [illegible] R [illegible] 5 [illegible] 2.5 [illegible] 1 [illegible] 2.5 [illegible] TS (570~) [illegible] VS (0.002) [illegible] 1.5 [illegible] 250 [illegible] "Colour of liquids" [illegible] (53 [illegible] 1 [illegible]).

[illegible] **Related substances** [illegible] R1 [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatoraphy" [illegible] 3 R [illegible] 10 R [illegible] 15 [illegible] Kieselguhr [illegible] TS (100~) [illegible] (B) [illegible] 1 [illegible] 5.0 [illegible] (A) [illegible] 3 [illegible] 10 [illegible] 1 [illegible] 0.20 [illegible] A [illegible] A [illegible] B [illegible] C.

[illegible] **Assay** [illegible] 0.03 [illegible] 1000 [illegible] 1 [illegible] 361 [illegible] $C_{63}H_{88}CoN_{14}O_{14}P$ [illegible] 20.7 $(E^{1\%}_{1cm} = 207)$

ØØØØØ

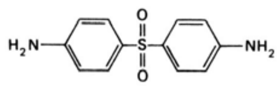
DAPSONUM

Dapsone [illegible]

[illegible] **Molecular formula** $C_{12}H_{12}N_2O_2S$

[illegible] **Relative molecular mass** 248.3

¦**Graphic formula** ǦƐφǺƐǤţǟ Ǧ8ƐÔöä



¦**Chemical name** ȔəǺƐŧƐÒöä ʖèɼǟ

4,4′-Sulfonyldianiline; 4,4′-sulfonylbis[benzenamine]; 4,4′-diaminodiphenylsulfone; CAS Reg. No. 80-08-0.

.ǦȞəäÀöä ƇƐȝ ÜȔƹÀõ ȒƐǚ şǚ ȒƐǚ ƁøźƗ àźȞÊɳ ¦**Description** ȤòȤöä

Ž āȁşæ ÜTS (ò/ȟ 750~) òȤφǺǯǺqǟ ȡɳ ǺõÂDZ 30 Žş òǺţǟ ȡɳ òÂDZ 7000 Ž āȁşæ ¦**Solubility** ǦƐφǺæşØöä

.R ȷȤǪƐèɟǟ

.ÿäØƉzŸö åǺȒɳ ¦**Category** ǦǺÀöä

.òȤȒöä ȡɳ ǦƐŧȚ ÛÿǺÒǵüæ ǦǑŸ8ɳ ǦÀşǺǵ Ž ȷȤÊääÆöä ȘǺǵ Ƶ ¦**Storage** ȡÀÂǺǪöä

ÛƐüÀöä ƁȤƨǟ 8Ÿ8Ÿö ôÀȞǪöä ʔƐö ƐzøƐǩ ȷȤÊääÆöä ȭøƐǪÀ ¦**Additional information** ǦƐźǺȑǚ ǧǺɳȤŸȞɳ

.ǦƐöǺȞöä ǥøäÀΣǟ ǧǺDZøǻ ƐÀȝ ţǺèǚ ȮƉǺǪöä ȷȤÒÀş òȤȒöä āǺƐȡ Ž ʔøǪǵ

REQUIREMENTS ƘǦǚƱƙdž!ƒ

ȡɳ %101.0 ȡȝ ƐÀÂÀ ɼş %99.0 ȡȝ ȮȭÀ Ǻɳ ʔŸȝ ȷȤÊääÆöä ƁȤǪƷ ¦**General requirement** ÿǺȞöä ƐŸÛǪţǟ

.ǦǺǺDzţǟ ǥǻǺţǟ ƂǚţȤDZÀöǺæ ǦæȤÊȚ Û$C_{12}H_{12}N_2O_2S$

¦**Identity tests** ǆǏǊǋǇǁ ǐǁǅƑǦǶƜǁ

ƙǟ Ǻɳ ǯǟȤɳɟǟ òǟȤüǚ Ž ƐŁǺÎÀ ǺɳƐȝ ÛR òȤφǺǯƐţǟ Ž ȬɳƆÿäÀȡşÀÒɳ 5.0 ÂƐȭÀǪæ òȤŸȚ îǺÔǪɳǟ ȤƐü ƁƐǦÀ :A

ǦȭǦü òŸǹ ȡɳ ȷǺȍǺŧǪöä ɳŸǦÀ ÜÀǪɳȤφǺφ 295ş ÀǪɳȤφǺφ 260 ǦǟäÀę ƐÀȝ ƐŧȚȝǚ ƐòǺÔǪɳǚ ÜÀǪɳȤφǺφ 350ş ÀǪɳȤφǺφ 230

.Ƃǟ ȤǪöä ʔŸȝ Û1.20ş 0.72 ǦǟäÀę ÀǪɳȤφǺφ 295ş ÀǪɳȤφǺφ 260 ƙǪƐŧȚȝɟǟ ƙǪDZȤţǟ ƂȤü ƐÀȝ ʖè 1 ǦφǺǺǯæ

ȡɳ ǦƟǺÀöä ǦƐÊƐəÀöä ǦȞȭǦöä ȨæǺÛǪǩ ."Related substances ǦõǺÎţǟ åǟȤţǟ" ȷǟȤÀȝ ƘƠ ǺȭǵɼǺ øǺǦǪǹɼǟ ÀȚφǟ :B

.B òȤŸɟǟ ȡɳ ǰǪÀǩ ȔøǪöä ǦƐÊƐəÀöä ǦȞȭǦöä ȝɳ ǥƐÎöäş ÀƬȚţǟş ǯȇȤţǟ Ž A òȤŸɟǟ

ǧǟøǺǦǪǹǟ" ȷǟȤÀȝ ƘƠ ǦǺöşɟǟ ǦƐǩǺɳşøɟǟ ǧǺÀƐɳɟǟ 8ǟÀȞǪèǟ ȬDZɟ 8ȤòȤţǟ ȬȝǺÀǪöä ȟ 0.1 ǦǟäÀę ȔÛȞ :C

.øǟÀþqǟ ǥƐÀƐì ǦæÀèø ǰǪǺǩş (119 ǦȔÀÔöä Û1 ƐŸÕä) "General Identification tests ǦɳǺȞöä 8ǟÀȞǪèɼǟ

.°ÿ 178 ǦǟäÀę ÛøǺƬÔφqǟ ǥøǟÀǵ ǦDZøǻ :D

.ȟ/ɳŸɳ 1.0 ȡȝ ƐÀÂÀ ɼ ¦**Sulfated ash** ƘǺŸÊţǟ åǺɳÀöä

Loss on drying: 105 ... 15 ...

Related substances: "Thin-layer chromatography" (84 ... 1) ... R3 ... R ... 4 ... R ... 8 ... 10 ... (A) ... 5 ... 10 ... (B) ... 1 ... RS ... 10 ... (C) ... 1 ... 0.15 ... (D) ... 1 ... 20 ... (E) ... 1 ... 0.10 ... 4,4′-thiodianiline RS ... 1 ... 4,4′-thiodianiline RS ... 100 ... TS2 4-dimethylaminocinnamaldehyd ... A ... C ... D ... E.

Assay: "Nitrite titration" (... 1) ... 15 ... 15 ... 0.25 ... (133 ... 1 ... VS (0.1 ...) ... TS (70~ ...) ... 12.42 ... $C_{12}H_{12}N_2O_2S$.

ØØØØØ

DEXAMETHASONI ACETAS

Dexamethasone acetate

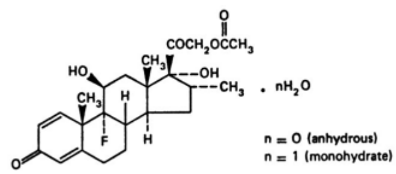
anhydrous

monohydrate

Molecular formula: $C_{24}H_{31}FO_6$ (...), $C_{24}H_{31}FO_6, H_2O$ (...).

Relative molecular mass: 434.5 (...), 452.5 (...).

Graphic formula



Chemical name

9-Fluoro-11*β*,17,21-trihydroxy-16*α*-methylpregna-1,4-diene-3,20-dione 21-acetate; 21-(acetyloxy)-9-fluoro-11*β*,17-dihydroxy-16*α*-methyl-pregna-1,4-diene-3,20-dione; CAS Reg. No. 1177-87-3 (anhydrous).
9-Fluoro-11*β*,17,21-trihydroxy-16*α*-methylpregna-1,4-diene-3,20-dione 21-acetate monohydrate; 21-(acetyloxy)-9-fluoro-11*β*,17-dihydroxy-16*α*-methyl-pregna-1,4-diene-3,20-dione monohydrate; CAS Reg. No. 55812-90-3 (monohydrate).

Description

Solubility 40 (~750) R.

Category

Storage

Labelling

REQUIREMENTS

General requirement %96.0 %104.0 $C_{24}H_{31}FO_6$

Identity tests

- A B C D E ; B C D E.

A: (43 1) "Spectrophotometry in the infrared region RS *reference spectrum*

reference ƟȞDZȀţä ȤȅÛöä 3ŋ şǕ RS ǧäǿǼȽȽä ǦȂåȦǵǕ ȷşàȀǪŋȦÊȮȂǼöä ǧȀǪȅèǕ ȡŋ ǰǪȂ ȾǾöä ȤȅÛöä 3ŋ ǧäǿǼȽȽä
. ǧäǿǼȽȽä ǦȂåȦǵǕ ȷşàȀǪŋȦÊȮȂǼöä ǧȀǪȅèɉ *spectrum*

ǼȂǾţȦæ Ōŋ 20 ȴDzǵ ƂǕ Ōŋ 2 ȤȁȂȽş TS (ȯ/ȟ 750~) ȯȥǫȂǯȂɋä ȯȥǗȚ ȡŋ Ōŋ 20 Ž ȠǗŋ 22 ǡäǾȂ :B
ŌȅȂȅȥ ȯȥǗȚ ȡŋ Ōŋ 10 ÛgåäǼè Ƀæ ǿȀǪǹȑä ǡȥǪǕ Ž Ǧ3ȥȑȥŋ ȯȥǗǂä äǾȽ ȡŋ Ōŋ 2 ƂǕ 8ȦȒȽş .ȼÊȦǫ
ɍ .ȑȦǵ åȀȂȽş ǦŌȅęå 20 ǵǼŋ °ÿ 60 ǵǿäȀǵ ǦDZǿǼæ ƟǝȦŋ ÿȦƥ Ž ȡȂǺÊȽş Ûǯȁȶȴ ÛTS ŌȂǿȥȦǗÊöä Ȑƥ/ȡȂȀäǿǼȽ
ÈȅŌǩ ǧäKDzǵ ÿäǼǺǪèä ŌȒȦȂ) 0.42 ȡ3 ȀǪŋȥǫȦǫ 423 ǦäȀȩ ƟȶȚ3ǕǦDZȥŋ ȯȥù ǼȂ3 ȴè 1 ǦǫȦǺǯæ ǦŌǦù ȋȦǪ ŌŌȂ
.(ȴè 1 ǦǫȦǺǯæ ǦŌǦÛö ȋȦȶǪöä ǼÊ3ş ǡȦȅŌǗö ȴè 2

ǦȅÊȅǝȀöä 3ŌȂöä Ęȥäȥǩ ."Related steroids ǦŏȦȊţä ǧäǼȂşƘǪÊöä" ȷäȥȂ3 ǨƠ ȂȀǫǕ 8ȥȍȥţä ǿȀǪǹȑä ȀȚǫä :C
ǦȅÊȅǝȀöä ǦȞŌǦöä ǵǼȉş ȀȚȚŋ ȷǕ ƂǕ ǦȥȦȑǕ .B ȯȥǗǂä ȡŋ ǦƟȀȂöä ŌǗǩ 3ŋ 3ęȥţä Ž Cş A ƙȯȥǗǂä ȡŋ ǰǪȂǩ Ɵǿǫöä
.B ȯȥǗǂä ȡŋ ǦƟȦȂöä ŌǗǩ 3ŋ Ęȥäȥǩ A ȯȥǗǂä ȡŋ ǰǪȂǩ Ɵǿǫöä

Û1 ǼǗŎä) "Oxygen flask method ƙDzÊõɉä ǦǗDZȥǵ ǦŌȂȀù" ȷäȥȂ3 ǨƠ 8ȥȍȥŋ ȥȽ ȦȶȘ ǡäȀǪǵɋä ĘȂÛȽ :D
(ȯ/ȯȥŋ 0.01) ÿȥȂåȥÔöä ǼȅÊõşǿǼȽ ȯȥǗȚ ȡŋ 0.5 ȡŋ ǰȂȂŋş ǿȀǪǹȑä ǵåȦŋ ȡŋ ȠǗŋ 7 ÿäǼǺǪèȦæ Û(132 ǦȞȦÔöä
ȡȂǿäȀȅŌǕ ȯȥǗȚ ȡŋ Ōŋ 0.1 ȡŋ ǰȂȂŋ ƂǕ Ōŋ 0.1 8ȦȒȽ ÛǦȅǗȶȞöä ŌȶǪŎǩ ȦŋǼȂ3 . ȋȦŋ ŌåȦÊȘ ŏȦţä ȡŋ Ōŋ 20ş VS
ÛTS Zirconyl nitrate ŌȅǪȥȘȂȂȂöä ǧäȀǫ ȯȥǗȚ ȡŋ Ōŋ 0.1ş ȀDZàȦù ȀȒȞţä TS (ȯ/ȟ 1) ÿȥȂåȥÔöä ǧȀǪȥȦǗè
.Ǵȑäş ȀȂȍǕ ƂǕ ȯȥǗȞȶǗö Ȁƥɉä ȷȥǗöä ȯȥǼǪȂ

5 ǵǼŋ ƟǝȦŋ ÿȦƥ Ž VS (ȯ/ȯȥŋ 0.5) ȯȥǫȂǯȂǕ/ÿȥȅèȀǩȥǦöä ǼȅÊõşǿǼȽ ȯȥǗȚ ȡŋ Ōŋ 2 3ŋ ȟ 0.05 ȡȂǺÊȽ :E
ǰȂȂǩ ÜǦŌȅęå 1 ǵǼŋ ȤȅÛö ȥǕ ɁǗ3 ɁǗ8ȽşTS (ȯ/ȟ 700~) ŌȂǿȥȦǗÊöä Ȑƥ ȯȥǗȚ ȡŋ Ōŋ 2 8ȦȒȽş åȀȂȽ .ĘǝȦęå
.(ǿǾǕ ŌȶȞöä ɁȀDzȽ) ȦȚǪȞǝäǿ ȡŋ ȦȚȘäǿåǕ ȡȮȥ Ɵǿǫöä ÛŌȅǪȂɋä ǧȀǪȅèǕ

ȷȦÊȘȥȂǼöä Ž Ōŋ/ȠǗŋ 10 ȀȅŌȀǪæ ȯȥǗȚ ŌȶȞǪÊȽ :**Specific optical rotation** Ɵ3ȥȂöä ȾȀÔǦöä ȀȂşǼǪöä
. $[a]_{\mathrm{D}}^{20°\mathrm{C}} = +82 \text{ to } +88°$ ÜR

.ȟ/ȠǗŋ 5.0 ȡ3 ǼȂȂȂ ɍ ÜƙǨŸǦöä ȡŋ ǦŌǩȥæ ŌȶȞǪÊȽş ȟ 0.1 ȷȁȥȂ :**Sulfated ash** ǨȂǗÊţä åȦŋȀöä

ȒȦǺȦŋ Ü8ȑ ǨƠ °ÿ 100 ǵǿäȀǵ ǦDZǿǼæ ǨæǯȀöä ȷàȥöä Ɂǿǫǵ ȤȁDzȽ :**Loss on drying** ȤȅȂDzǪŌȦæ ǼŌȦöä
ǼŌȦȂ ɍ ÜƟǝȦŋŸöä ŌȮȊöä ŌDZɉ ǵåȦţä ȡŋ ȟ 0.5 ǦäȀȩ ŌȶȞǪÊȽ .(ĘǦǝà ȴǗŋ 5 ǦäȀȩ şǕ ȯȦȮèȦæȥǗȅõ 0.6 ɁǼȞǪȂ ɍ)
ȀǯõǕ ɍş ȟ/ȠǗŋ 35 ȡŋ ŌęǕ ǼŌȦȂ ɍ Üǧäǿ ǼȽȽä ǦȂåȦǵǕ ŌDZɉ ǵåȦţä ȡŋ ȟ 0.15 ǦäȀȩ ŌȶȞǪÊȽş .ȟ/ȠǗŋ 0.5 ȡŋ ȀǯõǕ
.ȟ/ȠǗŋ 45 ȡŋ

ǦŌǦÛöä ǡäȀȊǪèä" ȷäȥȂ3 ǨƠ 8ȥȍȥŋ ȥȽ ȦȶȘ ǿȀǪǹȑä ĘǪÛȽ :**Related steroids** ǦŏȦȊţä ǧäǼȂşƘǪÊöä
ǰȂȂŋş ǦǗǾȠ ǵåȦȶȘ R1 ȦȮȅǗÊöä ǦŋŸȽ ÿǼǺǪÊȂş Û(84 ǦȞȦÔöä Û1 ǼǗŎä) "Thim-layer chromatography ǦŌȅęȀöä

[illegible] 1.2 [illegible] R [illegible] 8 [illegible] R [illegible] 15 [illegible] R [illegible] 77 [illegible] R [illegible] 9 [illegible] 1 [illegible] 15 [illegible] :(B) [illegible] 1 [illegible] 15 [illegible] :(A) [illegible] R [illegible] 1 [illegible] :(C) [illegible] 2 [illegible] 1 [illegible] RS [illegible] 0.15 [illegible] :(D) [illegible] 1 B A [illegible] .B A [illegible] 1 [illegible] 10 [illegible] 105 [illegible] TS [illegible] .D [illegible]

Assay [illegible]

- [illegible]

TS (750~ [illegible]) [illegible] 20 [illegible] 20 [illegible] 100 [illegible] 25 [illegible] 10.0 [illegible] 100 [illegible] TS (750~ [illegible]) [illegible] TS [illegible] 2.0 [illegible] TS [illegible] 2.0 [illegible] .R [illegible] .R [illegible] 30 [illegible] 1 [illegible] 1 [illegible] 25 [illegible] TS (750~ [illegible]) [illegible] 10 [illegible] 525 [illegible] $C_{24}H_{31}FO_6$ [illegible] TS (750~ [illegible]) [illegible] RS [illegible]

ØØØØØ

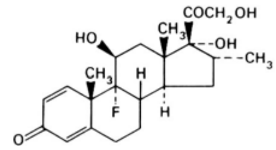
DEXAMETHASONUM

Dexamethasone [illegible]

[illegible] **Molecular formula** $C_{22}H_{29}FO_5$

392.5 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione; CAS Reg. No. 50-02-2.

:**Description**

:**Solubility** (~750) TS

.R

.Adrenoglucocorticoid :**Category**

:**Storage**

REQUIREMENTS

%96.0 :**General requirement**

$C_{22}H_{29}FO_5$ %04.0

:**Identity tests**

• .D C B / C B A

:A "Spectrophotometry in the infrared region" (1 43).

RS *reference spectrum*

.RS

:B 20 20 (~750) TS 20 2 20

2 10

TS 60 20

0.42 423 1 2

1

"Related steroids" :C

B. A C B

B. A

"Oxygen flask method" :D

(0.01 132 7 0.5

20 TS 0.1 0.1

sodium alizarinsulfonate TS (1/ 0.1

Zirconyl nitrate TS

Specific optical rotation: 10 R

$[a]_{\mathrm{D}}^{20\,°\mathrm{C}} = +72 \text{ to } +80°$

Sulfated ash: 0.1 5.0

Loss on drying: 100

0.6 5 5.0

Related steroids: "

"Thim-layer chromatography" (84 1 R1

R1 15 R 8 R 1.2 77

R 9 1 15

(A): 15 (B): 1 15 1

(C): 2 1 RS 1

1 0.15 (D): 1 B A

B A

10 105

TS

D A

Assay:

•

ǒÅÛʒq TS (ȯ/ȟ750~) ÆĿŁÆȫɟä ȸŋ БÅʅä ȯζφÅǯÅqä ȸŋ ǦĿζÅȭ ǦĿȶȭ Ž ÛǦĿüζǦȒŋ Ǧφʂàζŋ ÛŋŸŋ 20 ǦäÅȩ ȁäØŀ TS (ȯ/ȟ750~) ÆĿŁÆȫɟä ȸŋ БÅʅä ȯζφÅǯÅqä ȸŋ ǦĿζÅȭ ǦĿȶȮä ȯζŸǂä äØŁ ȸŋ Ȭŋ 20 ƸÅÅÁŀ .Ȭŋ 100 øÆȫä ʅDzǵ ÅĿȶDzǵ ǦDZøÆŋ Ȭŋ 25 ʅDzǵ ğäæ ǦŸDZζǵ БÛ ƸÅÅÁʈä ȯζŸǂä ȸŋ Ȭŋ 10.0 ȬʠÅŀ .Ȭŋ 100 øÆȫä ʅDzǵ ǒÅÛʒq ȸŋ БÅʅä ƙDZʂÅQÅöä ǦÛȅäζæ ǦŸDZζΣä ȸŋ ǒäζTä åÅÛŀʂ TS ȯζφÅǯÅqä/ÿζĿöʂàäÅQQöä Ǧçøȁ ȯζŸȚ ȸŋ Ȭŋ 2.0 ȣÅȒŀʂ gÅŋ ǒäζTä åÅÛŀʂ TS ȯζφÅǯÅÜ/ÿζĿφζŋɟä ȬĿǯŋ Ʉʒåäó ÆĿÊȭʂøÆĿŁ ȯζŸȚ ȸŋ Ȭŋ 2.0 ȯÅΣä Ž ȣÅȒÅʂ .R ƙDZÊȭǧä øäÅȬQȅŸö ȭÅQŀʂ ƸĿÅʅä ÅÅʂÆQäæ ğÅÅζQǂä ǯÂȶŀ Û ǦŸDZζΣä ǽÊŀ .R ƙDZÊȭǧä ȸŋ БÅʅä ƙDZʂÅQÅöä ǦüÅȅζæ ǦĿφÅǫ ȸŋ БÅʅä ȯζφÅǯÅqä ȯζŸȚ ȸŋ ǦĿζÅȭ ǦĿȶȭ ȣÅȒŀʂ ǦʒÅÊæ åÅÅŀ .°ÿ 30 gøÅǵ ǦDZøÆæ ɄəÅŋ ÿÅþ Ž ǦʒÅȅ 1 gÆŋ ǦDZζŋ ȯζü ÆÅʒ ʅȅ 1 ǦφÅÁǯæ ǦȬǦü ȋ ÅQ ȃÅȫŀ .ǯÂȶŀʂ Ȭŋ 25 øÆȫä ʅDzǵ ǒÅÛʒq TS (ȯ/ȟ750~) ÆĿŁÆȫɟä ȸŋ БÅʅä ȯζφÅǯÅqä ȯζŸȚ ȸŋ Ȭŋ 10 ǦƨÅȞŋ ÅÅȒɄŀ ĿζŸȚ ɃζƠ ÆÅØŋ gƘDzǵ ȬäÅȬŋ ÅQŋζφÅφ 525 ǦäÅȩ ɄȶȚʒÜ ȷʂäÅQĿŋÅÊȮÅÆöä ʒŋ ǦφøÅȬʈÅæ gÅÅQÅÁʈä gåÅʈä Ž $C_{22}H_{29}FO_5$ øäÆȫŋ ÆÊɄŀ .¢äÅȊŋ ȁζŸȅüæ TS (ȯ/ȟ750~) ÆĿŁÆȫɟä

.ȸŋäÅQöäʂ ǦǒÅȊʈÅæ ȋζɄÅʈä RS

ØØØØØ

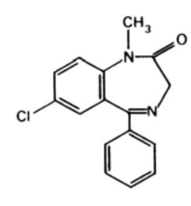
DIAZEPAMUM

Diazepam !ƑǦĩȐƑĩŋ

$C_{16}H_{13}ClN_2O$ ¦**Molecular formula** ǦĿÅÅÂƨä Ǧ8ĿÔöä

284.7 ¦**Relative molecular mass** ǦĿǦÊÅöä ǦĿÅÅÂƨä ǦŸQȮöä

¦**Graphic formula** ǦĿφÅĿǦʈä Ǧ8ĿÔöä



¦**Chemical name** ɄəÅĿȶĿȮöä ʅȅɍä

7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2*H*-1,4-benzodiaze-pin-2-one; CAS Reg. No. 439-14-5.

.ǦɄəäÅöä ƇÆʒ ÅǦÅÅȬǩ ʂÜ ǦɄəäÅöä ƇÆʒ ÜȒĿäÜ ÅǦÅÅȬǩ ʂÜ ȒĿäÜ ȷζŸæ ɃøζŸæ ȧζɄÊŋ ¦**Description** ƸȍζØä

Ž ȷÅæʂØöä Åǵ ÜTS (ȯ/ȟ750~) ȯζφÅǯÅqä Ž ȁäʂæ ÜǒÅʈä Ž ÅÆDZ ȷÅæʂØöä ǴĿɄȉ ¦**Solubility** ǦĿφÅæʂØöä

.R ÿǿǳȘǿǳŸÒöä

.Tranquilizer ÙǢǮħ :**Category** ĞÅÄöä

.öǳȒöä ȸɳ ǴȽȶȚ ÛǢǢǄǲ ĞÕŸ8ɳ ǴȘÅǵ Ž ÿÅǴàÅǢöä ȘÅǵ Ǣƶ :**Storage** ȸÂÅǪöä

REQUIREMENTS ƘǴǗǷǩdž!ƒ

ȸɳ %101.0 ȸȝ ǢÂÂ ɍȘ %99.0 ȸȝ ÕÕÂ ɍ Åɳ ɁŸȝ ÿÅǴàÅǢöä ɃǭǬȜ :**General requirement** ÿÅĦöä ǢŸÛǪțä
.ĞÅÅÒä ǵÅțä ƃÜ țǳǱÀöÅǽ ǴǽǳÊȚ Û$C_{16}H_{13}ClN_2O$

:**Identity tests** ħǏǋǊǁƐ ǀ ƐƥƒǴƗǪƐ

.Dȿ Cȿ B ǧäǿÅǴǪǹɍä ȿÜ Dȿ A ȸÅǿÅǴǪǹɍä ÅɳÜ ȨǢǴÛǨ ȸÒǳ •

âÅÕǩȿ low-actinic glassware ĞȒÅÅÅɳ ǴǢǢǪõÜ ǧäǽ ǴǢǳǱÀǳà ǴǢǬÜ Cȿ B ȸÅǿÅǴǪǹɍä Õǲǰ ÿǢÅǪÊÂ :ǦȚǵŸɳ
.ĞÕǢȩå 30 ȯŸǹ

öäÀȶΣä ǨƠ ĞĦǐǰä ĞÕÛÅɳ Ž ɄǝȒöä ǬǢÛöä âÅǢȩ" ɉäǳȜ ǨƠ 8ǳòǳɳ ǳȽ ÅȶȭǑĦÅöä ɁÀǱƚ :A
ǨƠ ĞĦǐǰä Ž ȋÅÔǪɳɍä ǬǢù ȨǽÅÛǪÂ .(43 ĞĦÅÔöä Û1 ǢŸÕä) "Spectrophotometry in the infrared region
.*reference spectrum* ÿÅǴàÅǢŸö ɄĦǱÀțä ǬǢÛöä ȝɳ ȿÜ RS ÿÅǴàÅǢöä ȸɳ ǰǪÅÂ ɃǾöä ǬǢÛöä ȝɳ öäÀȶΣä

VS (ȯ/ȯǳɳ 0.1) ÕÅǿǳŸȭȿǿǢǢŢä ȒƥȯǳŸȚ Ž Õɳ/ÿäÀǳȿÀȯɳ 8.0 ÂǢȭÀǪǽ ȯǳŸȚ ȋÅÔǪɳä ǬǢù ɃǢǴƚ :B
286ȿ ÀǪɳǳǳǳ 241 ĞǽäÀǢ ǢÅȝ ǴȽȚȝÜ ǧÅòÅÔǪɳä ÀǪɳǳǳǳ 350ȿ ÀǪɳǳǳǳ 230 ƙǽ Åɳ ǯäǳɳɉä ȯäǳùÜ Ž ǢȽÅÎƚ ÅɳǢÅȝ
ɁŸȝ Û0.38ȿ 0.80 ĞǽäÀǢ ÀǪɳǳǳǳ 286ȿ ÀǪɳǳǳǳ 241 ǯäǳɳɉä ȯäǳùÜ Ž ǈè 1 ĞǪÅÅǯǽ ĞÕǴÛö ǧÅǹÅȶǪöä ɉǳÒǨ ÜÀǪɳǳǳǳ
.(ǈè 1 ĞǪÅÅǯǽ ĞÕǴÛö ȋÅȶǪöä ǢÊȜȿ âÅǢÕŸö ǈè 2 ÈǢÕǨ ǧäƘǲǵ ÿäǢÅǪèä ÕȒÅÂ) ƃäǳǪöä

ÅɳǢÅȝ VS (ȯ/ȯǳɳ 0.1) ÕÅǿǳŸȭȿǿǢǢŢä ȒƥȯǳŸȚ Ž Õɳ/ŋŸɳ 0.030 ÂǢȭÀǪǽ ȯǳŸȚ ȋÅÔǪɳä ǬǢù ɃǢǴƚ :C
ȋÅǪ ɉǳÒÂ ÜÀǪɳǳǳǳ 362 ĞǽäÀǢ ǢÅȝ ǢȽȚȝÜ ǢòÅÔǪɳä ÀǪɳǳǳǳ 400ȿ ÀǪɳǳǳǳ 325 ƙǽ Åɳ ǯäǳɳɉä ȯäǳùÜ Ž ǢȽÅÎƚ
ȋÅȶǪöä ǢÊȜȿ âÅǢÕŸö ǈè 2 ÈǢÕǨ ǧäƘǲǵ ÿäǢÅǪèä ÕȒÅÂ) 0.44 ĞǽäÀǢ äǾȽ ǴǱǳțä ȯǳù ǢÅȝ ǈè1 ĞǪÅÅǯǽ ĞÕǴù
.(ǈè 1 ĞǪÅÅǯǽ ĞÕǴÛö

Û1 ǢŸÕä) "Oxygen flask method ƙǲÊȭɉä ĞŸǲǳǵ ĞÕÅÀù" ɉäǳȜ ǨƠ 8ǳòǳɳ ǳȽ ÅȶȭǑȧäÀǪǵǪä ȨǢÛƚ :D
TS (ȯ/ħ80~) ÿǳÅåǳÔöä ǢǢÊȭȿǿǢǢȽ ȯǳŸȚ ȸɳ Õɳ 5ȿ ǿÅǴǪǹɍä ǵÅɳ ȸɳ ŋŸɳ 20 ÿäǢÅǪèÅǽ Û(132 ĞĦÅÔöä
ÜĞÕǢȩå 2 ǵǢɳ ǬÛŸǽ ɁŸ8ȿ TS (ȯ/ħ100~) ÕÅǿǳÅŸÊöä ȒƥȯǳŸĦɳ ȒȽĦƚ Û ÕȶĦöä ȯÅȶȭÜ ǢÅȝȿ .ɳȋ Åɳ ÕǝÅÊȭ
"General identification tests ĞɳÅĦöä 8äÀĦǪèɍä ǧäǿÅǴǪǹä" ɉäǳȜ ǨƠ 8ǳòǳțä ÛA ÕȝÅǪöä ȯǳŸɉä ɄÛĦƚ
.(121 ĞĦÅÔöä ÛǢŸÕä) ǧäǢÅǿǳŸÒŸö ÂǢȶħ ÕȝÅǪȭ

[illegible] **Melting range**: 131-135°.

[illegible] **Heavy metals**: [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 3 [illegible] 127) [illegible] A [illegible] 128) [illegible] 20 [illegible].

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible].

[illegible] **Loss on drying**: [illegible] 50° [illegible] 0.6 [illegible] 5 [illegible] 5.0 [illegible].

[illegible] **Related substances**: [illegible] "Thin-layer chromatography" [illegible] 84) [illegible] R2 [illegible] 24 R [illegible] 1 [illegible] 0.20 [illegible] (A): [illegible] R [illegible] 10 [illegible] 5-chloro-2- [illegible] -2- [illegible] -5 [illegible] 0.10 [illegible] (B): [illegible] 1 [illegible] 1 [illegible] methlaminobenzophenone RS [illegible] A [illegible] 254) [illegible] B.

[illegible] **Assay**: [illegible] 0.55 [illegible] 30 [illegible] R1 [illegible] 0.1) VS [illegible] 1 [illegible] "Non- aqueous titration [illegible] A [illegible] 142) [illegible] 0.1) VS [illegible] 28.47 [illegible] $C_{16}H_{13}ClN_2O$.

[illegible]

Additional requirements for Diazepam for parenteral use

[illegible] "*Parenteral preparations*" [illegible] 4 [illegible] 56).

[illegible] **Bacterial endotoxins** [illegible] "Test for bacterial endotoxins" [illegible] 5 [illegible] 30 [illegible] 11.6 [illegible] RS [illegible] 1 [illegible].

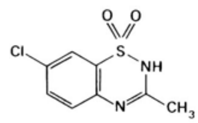
DIAZOXIDUM

Diazoxide ợǐƨǀǸƦĩƞ

$C_8H_7ClN_2O_2S$ ¦**Molecular formula** ǦƎȦǺƨä Ǧ8ƎÔöä

230.7 ¦**Relative molecular mass** ǦƎǴÊǺöä ǦƎȦǺƨä ǦŸǪỎöä

¦**Graphic formula** ǦƎǾȦƎǤţä Ǧ8ƎÔöä



¦**Chemical name** ȾəȦƎŧƎỎöä Ḷèɍä

7-Chloro-3-methyl-2*H*-1,2,4-benzothiadiazine 1,1-dioxide;
CAS Reg. No. 364-98-7.

.ǦȾəäȀöä ƇƎʒ ǕƎǤȀÖǩ ȐƎȁ şȕ ȐƎȁ Ƀøζǽ ȧζȾÊņ ¦**Description** Ⱬòζöä

ȾəȦȀǭ Ž ɉȦǽşǾöä Ȁǵ ǕR ỹøζζşøζŸỎöä Ž ɍş R Ǩǭɉä Ž ɍş ŏȦţä Ž ȦƎŸŧʒ ā ȧşǽ Ƙȡ ¦**Solubility** ǦƎǾȦǽşǾöä
.TS (ȯ/ȟ750~) ȯζǾȦǮǺqä ȯζŸȚ Ž ɉȦǽşǾöä ǴƎȾȉ ǕR ǼƎņȦņøζζ ŌƎǮƎņ

.Antihypertensive ỹǼƎöä Ȕ8ȑ ȐǭȦȵ ¦**Category** ǦȦȦöä

.ȦƎǼƎǲ ǦǑŸ8ņ ǦȀşȦǵ Ž ǼƎÊõşäȦȀǼöä Șȧǵ Ǽʑ ¦**Storage** ȸȀÂǺǪöä

REQUIREMENTS ƘǦƎǔƱǩǳ!ƒ

%101.0 ȸʒ ǼȀÂȀ ɍş %98.0 ȸʒ ŌȀ ɍ ȦņȥŸʒ ǼƎÊõşäȦȀǼöä Ƀζǫʒ ¦**General requirement** ỹȦȞöä ǼŸÛǪţä
.ǦȦȦǱţä ǵȦţä ȻǕ ţζǱȀȦǽ ǦǽζÊȚ Û$C_8H_7ClN_2O_2S$ ȸņ

¦**Identity tests** ƕǐǸǇǁ ǀ ƐƥƑƗƢƐ

ŏäȀŧƩä ƘƠ ǦȞȉɉä ǦŎÛȦņ Ž ȾəζȒöä ⱫƎÛöä ȃȦǽ" ɉȧζȦʒ ƘƠ 8ζòζņ ζȽ ȦŧỗǑȾȀöä ȜȀǳɫ :A
ƘƠ ǦȞȉɉä Ž ȋȦÔǪņɍä ⱫƎȕ ȨǽȦÛǪȀ .(45 ǦȾȀÔöä Û1 ǼŸǑöä) "Spectrophotometry in the infrared region
.ǼƎÊõşäȦȀǼŸö *reference spectrum* ȾȞǱȀţä ⱫƎÛöä ʒņ şȕ RS ǼƎÊõşäȦȀǼöä ȸņ ǰǪȀ ɃØöä ⱫƎÛöä ʒņ ŏäȀŧƩä
ǦƎÊƎəȀöä ǦȞŌǤöä Ȩζäζǩ ."Related substances ǦŏȦÎţä ǻäζţä" ɉȧζȦʒ ƘƠ ȦŎǵɍ 8ζòζţä øȦǪņɍä ȀȚǾä :B
.C ȯζŸǂä ȸņ ǦƟȀȀöä ŌŸǩ ʒņ ǵǼÎöäş ȀȚȚţäş ʒǨζţä Ž B ȯζŸǂä ȸņ ǰǪǩ Ⱦøǭöä

.ȟ/ŋŸņ 1.0 ȸʒ ǼȀÂȀ ɍ ¦**Sulfated ash** ƘȦǼŸÊţä ǻȦņȀöä

5.0 ﻦﻣ ﺮﺜﻛﺃ ﺪﻘﻔﻳ ﻻ ﺔﺟﺭﺩ 105 ﺪﻨﻋ ﻲﻧﺍﺮﺒﻟﺍ ﺦﻳﺮﻄﻟﺍ ﺐﻃﻮﻟﺍ ﻦﻋ ﻥﺍﺪﻘﻔﻟﺍ :**Loss on drying** ﻥﺍﺪﻘﻔﻟﺍ ﺪﻨﻋ ﺍﻟﺘﺠﻔﻴﻒ .ﺔﺌﻤﻟﺎﺑ

ﺔﻘﻴﻗﺪﻟﺍ ﺔﺟﺭﺪﻟﺍ ﺕﺍﺫ ﻖﺋﺎﻘﺤﻟﺍ "ﻲﻘﻴﺤﻟﺍ ﺩﻮﻤﻌﻟﺍ ﺓﺭﺎﺼﻌﻟﺍ ﻥﺰﺧ :**Related substances** ﺔﺒﻴﺑﺎﻘﻟﺍ ﺓﺩﺎﻤﻟﺍ 17 ﻦﻣ ﻞﻜﻟﺍ ﺔﻔﻋﺎﻀﻤﻟﺍ R2 ﻲﻠﻟﺎﻜﻟﺍ ﻊﻣ ﻱﺬﻟﺍ ﺔﻴﻠﻠﻠﺍ ﻲﻓ(84 ﺔﻠﻤﺘﺤﻟﺍ ﻲﻓ1 ﺔﻤﻠﻛ) "Thin-layer chromatography ﻲﻓ TS (ﻭ/ﺡ260~) ﺔﻘﻴﻗﺭ ﺔﻘﺒﻃ ﻦﻣ ﻒﻠﻐﻟ 3ﺔ R ﺔﻘﺒﻃ ﻦﻣ ﻒﻠﻐﻟ 4ﺔ R ﻞﻴﻟﺪﻟﺍ ﻲﻓ ﻦﻣ ﻂﻠﺨﻟ (ﻭ/ﻭﺣ 0.1) ﻲﻧﻮﺗﺎﻟﺍ ﻞﻴﻠﺤﻤﻟﺍ ﺔﻘﺒﻃ ﻲﻓ ﻞﺋﺎﺳ ﻒﻠﻐﻟ ﻦﻣ ﻲﻟﺎﻤﺘﺣﺍ 10 ﺔﻠﻤﺘﺤﻟﺍ ﺔﻴﻠﻜﻟﺍ ﺓﺭﺎﺼﻋ .ﻯﺮﻐﺻ ﻲﻓ ﻞﺋﺎﺴﻟﺍ ﻊﻣ ﻦﻣ ﺔﺌﻣ 0.15 ﺪﺣﺍ :(B) ﺔﻘﻴﻗﺭ ﻞﻣ 1 ﻲﻓ ﻞﺋﺎﺴﻟﺍ ﻊﻣ ﻦﻣ ﺔﺌﻣ 15 ﺪﺣﺍ :(A) ﺔﻘﻴﻗﺭ ﻲﻓVS ﺔﻓﺎﻀﺑ ﻦﻣ ﺔﻠﻤﺘﺤﻟﺍ ﺔﻴﻟﺎﻌﻓ ﺔﻳﺩ .ﻞﻣ 1 ﻲﻓ RS ﻞﻴﻠﺤﻤﻟﺍ ﻦﻣ ﺔﺌﻣ 0.15 ﺪﺣﺍ :(C) ﺔﻘﻴﻗﺭ ﻞﻣ 1 ﻲﻓ ﺔﻘﻴﻗﺪﻟﺍ ﺓﺮﻳﺮﺣ ﻝﻮﻄﻟﺍ ﻲﻓ ﻥﻮﻜﻳ ﺔﻳﺎﻬﻧ ﺔﻘﻴﻗﺭ ﺔﻠﻴﻔﻛ ﺐﻃﻮﻟﺍ ﻂﻘﻓ ﻲﻓ ﻥﺍﺮﻘﻟﺍ ﻰﺘﺣ ﻲﻓ ﺔﻘﻴﻗﺪﻟﺍ ﻦﻣ ﺲﻤﻟ ﺮﺜﻛﺃ ﻲﻓﺎﻀﻟﺍ ﺔﺒﺴﻨﻟﺍ ﺔﻴﻟﺎﻌﻓ ﻲﻓA ﺔﻘﻴﻗﺭ ﻦﻣ ﻞﻜﻟﺍ ﺔﻴﻃﺎﺑ ﻑﻭ ﺭﻮﻛ ﺭ .(ﺔﻣﻮﻗﺎﻣ 254) ﺔﻴﻟﺎﻌﻟﺍ ﻉﻭ ﺔﺒﻴﻄﻣ .B ﺔﻘﻴﻗﺭ ﻦﻣ ﺔﻌﻠﻟﺍ ﻯﺮﻗ

ﻞﻴﻟﺩ ﺔﻔﻟﺎﻣ ﻦﻣ ﻂﻠﺨﻟ 2 ﻦﻣ ﻞﻜﻟ ﻦﻣ ﻞﻣ 100 ﻲﻓ ﻲﻓﻮﺗﺍﺮﻟﺍ ﻊﻓﺮﻟﺍ ﻲ ﺡ 0.45 ﺔﻠﻘﻟ ﻕﺮﻃ :**Assay** ﺔﻴﻟﺎﻌﻟﺍ ﺔﻴﻧﺎﻜﻟﺍ ﺔﺜﺣﻮﺒﻟﺍ ﺔﻟﺎﻬﺠﻟ VS (ﻭ/ﻭﺣ 0.1) ﻲﻧﻮﺗﺎﻟﺍ ﻞﻴﻠﺤﻤﻟﺍ ﺔﻘﺒﻃ ﺔﺒﺻﺎﻨﻟﺍ ﺔﻠﻘﺘﺴﻣ ﺔﻟﺎﻤﺟ ﻦﻣ ﻂﻠﺨﻟ 1ﺔ R ﻞﻤﻌﻟﺍ ﻦﻣ ﺔﺌﻣ 23.07 ﻲﻓﺎﻜﻳ VS (ﻭ/ﻭﺣ 0.1) ﻲﻧﻮﺗﺎﻟﺍ ﻞﻴﻠﺤﻤﻟﺍ ﺔﻘﺒﻃ ﻦﻣ ﻞﻣ 1 ﻲﻓ .ﻞﻣﺎﻛ ﻥﺍﻮﻟﺃ .$C_8H_7ClN_2O_2S$

ﺄ ﺄ ﺄ ﺄ ﺄ

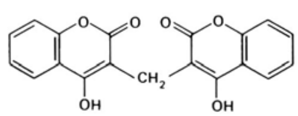
DICOUMAROLUM

Dicoumarol ﻝﻭﺭﺎﻣﻮﻜﻳﺩ

$C_{19}H_{12}O_6$:**Molecular formula** ﺔﻴﺌﻳﺰﺠﻟﺍ ﺔﻐﻴﺼﻟﺍ

336.3 :**Relative molecular mass** ﺔﻴﺒﺴﻨﻟﺍ ﺔﻴﺌﻳﺰﺠﻟﺍ ﺔﻠﺘﻜﻟﺍ

:**Graphic formula** ﺔﻴﻧﺎﻴﺒﻟﺍ ﺔﻐﻴﺼﻟﺍ



:**Chemical name** ﻲﺋﺎﻴﻤﻴﻜﻟﺍ ﻢﺳﻻﺍ

3,3′-Methylenebis[4-hydroxycoumarin]; 3,3′-methylenebis[4-hydroxy-2*H*-1-benzopyran-2-one]; CAS Reg. No. 66-76-2.

[illegible] :**Description** [illegible]

[illegible] TS (~750) [illegible] :**Solubility** [illegible]
.R [illegible]

.Anticoagulant [illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

%101.0 [illegible] %98.5 [illegible] :**General requirement** [illegible]
.[illegible] $C_{19}H_{12}O_6$ [illegible]

:**Identity tests** [illegible]

- .C [illegible] B [illegible] A [illegible]

:A [illegible]
[illegible] .(45 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region
.[illegible] *reference spectrum* [illegible] RS [illegible]

:B [illegible] 0.2 [illegible] 0.2 [illegible] 5 [illegible] R [illegible]
.([illegible]) [illegible] TS (~250) [illegible]
.C [illegible]

:C [illegible] 1 [illegible] B [illegible] 5 [illegible] 1 [illegible]
.[illegible] TS (~70) [illegible] 2 TS (25) [illegible]

.[illegible] 2.5 [illegible] :**Sulfated ash** [illegible]

5.0 [illegible] 105 [illegible] :**Loss on drying** [illegible]
.[illegible]

[illegible] 1 [illegible] R [illegible] 10 [illegible] 0.5 [illegible] :**Acidity** [illegible]
TS [illegible] VS (0.1) [illegible]
.([illegible]) [illegible] 0.1 [illegible]

[illegible] 5 [illegible] R [illegible]-1 [illegible] 40 [illegible] 0.35 [illegible] :**Assay** [illegible]

[illegible] VS (0.1 [illegible]) [illegible] azo violet TS [illegible] "Non-aqueous titration [illegible] 16.82 [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) .$C_{19}H_{12}O_6$

[illegible]

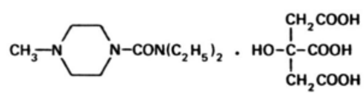
DIETHYLCARBAMAZINI DIHYDROGENOCITRAS

Diethylcarbamazine dihydrogen citrate [illegible]

$C_{16}H_{29}N_3O_8$ [illegible] $C_{10}H_{21}N_3O, C_6H_8O_7$:**Molecular formula** [illegible]

391.4 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

N,N-Diethyl-4-methyl-1-piperazinecarboxamide citrate (1:1);
N,N-diethyl-4-methyl-l-piperazinecarboxamide 2-hydroxy-1,2,3-propanetri-carboxylate (1:1); CAS Reg. No. 1642-54-2.

[illegible] :**Description** [illegible]

[illegible] TS (~750 [illegible]) [illegible] 35 [illegible] :**Solubility** [illegible] R [illegible] R [illegible]

.Filaricide [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

[illegible] :**General requirement** [illegible]

[illegible] $C_{10}H_{21}N_3O, C_6H_8O_7$ [illegible] %101.0 [illegible] %98.0 [illegible].

:**Identity tests** [illegible]

• [illegible] A [illegible] B [illegible].

A: [illegible] 0.05 [illegible] 25 [illegible] 1 [illegible] 80~) [illegible] TS [illegible] 4 [illegible] R [illegible] 2 [illegible] blank [illegible] R [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 0.5 [illegible] 10 [illegible] 10 [illegible]) VS [illegible] 4 [illegible] 5 [illegible] R [illegible].

[illegible] C [illegible] R [illegible] 1 [illegible] TS [illegible] 750~) [illegible] 5 [illegible] 105 [illegible] R [illegible] TS [illegible] 750~) 1-diethylcarbamoyl-4- [illegible]-4-[illegible] 1) [illegible] 152 [illegible] methylpiperazine ethiodide).

C: [illegible] B [illegible] B [illegible] "General identification tests [illegible] (121 [illegible] 1 [illegible]).

D: [illegible] 80 [illegible] 137 [illegible].

:**Heavy metals** [illegible] 1.0 [illegible] "Limit test for heavy metals [illegible] 1 [illegible] (127 [illegible] 1 [illegible]).

.ȟ/ÿäÀƌ şÀÒɳ 20 ȡȝ ÆÀÂÀ ɍ Ü(128 ǦĦÀÔöä Û1 ÆŸÕä) A ǦŌÀÛöä Ęzş ǦŸĒŎǯöä ȷåÀȞţä ʔzϘƬ ȡĦĦł .ȟ/ɳŸɳ 1.0 ȡȝ ÆÀÂÀ ɍ ¦**Sulfated ash** ǨÀŸÊţä åÀɳÀöä

Determination of water by ÀÎĘz òøÀõ ǦŌÀÀÛæ öÀţä ƙĦĦǩ" ȷäzÀȝ ǨƠ ȣzòzɳ zȽ Àŧõ ȡĦĦł ¦**Water** öÀţä ʔzϘƬ ÆÀÂÀ ɍ Ügåţä ȡɳ ȟ 1 ǦäÀę òÀŧĦϘèÀæş Û(145 ǦĦÀÔöä Û1 ÆŸÕä) A ǦŌÀÛöä Ûthe Karl Fischer method .ȟ/ɳŸɳ 10 ȡȝ öÀţä

.4.5 - 3.5 ÛŌɳ/ɳŸɳ 30 ÂĒõÀϘæ òzŸƬ öÀȽÀæ ɳŸǦÀ ¦**pH value** öÀȽÀǦöä Ǧŧęz

ǦŌǦÛöä ãäÀÎϘèä" ȷäzÀȝ ǨƠ ȣzòzɳ zȽ Àŧõ øÀǦϘǹɍä ĘĦÛł ¦***N*-Methylpiperazine** ȡÀàäƘĒæ ŌĒǯĘɳ-*N* ǰÀÂɳş ǦŸɃĦ gåÀŧõ R1 ÀÒĒŸÊöä ǦɳŸȽ ÿäÆǺϘèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸÕä) "Thin-layer chromatography ǦŌĒęÀöä øzÛõ öÀţä ȡɳ ÀŧDzǵ 1ş R ɄDzŸǯöä ŌĒϘèɟä Ȑþ ȡɳ ÿzDzǵ 3ş TS (ȯ/ȟ 750~) òzφÀǯÀqä ȡɳ ÿzDzǵ 6 ȡɳ ȡɳ ɳŸɳ 50 ɃzȜ :(A) òzŸɬä ÛR òzφÀǯĒţä Ž ƙÀϘä ƙòzŸƬ ȡɳ ÀϘöşÀÒɳ 5 ǦĦÀÔöä ʔŸȝ ŸÔÀÀɳ ĘĦÛł .õÀĦϘɳ 1 Ōõ Ž *N*-Methylpiperazine R ȡÀàäƘĒæ ŌĒǯĘɳ-*N* ȡɳ ɳŸɳ 0.050 ɃzȜ :(B) òzŸɬäş Ōɳ 1 Ōõ Ž øÀǦϘǹɍä gåÀɳ òzŸƬ ȡɳ ÿzDzǵ 3 ȡɳ ǰÀÂɳ òzŸĦɳ æÀł ÛöäzƬä Ž ȤDzϘö õÀϘł Ûã äÀÎϘèɍä gƘDzǵ ȡɳ ǦĦÀÔöä ţÂøφ ÆĦæş .Ōɳ ÛTS (ȯ/ȟ 60) ÿzĒèÀǩzǦöä ÆÀåzÀ òzŸƬ ȡɳ ȴDzǵ 100ş öÀţä ȡɳ ÀŧDzǵ 97ş TS (ȯ/ȟ 60) ƙǨŸǦöä ÆÀøzŸõ Ž ǦŌzäzϘɳ ÛǦǨŌæ ǦÀÛ ȡɳ ǦzÀǯõ ÆĦÛ B òzŸɬä ȡɳ ǦƟÀÀöä ǦǨŌǦöä ȷzÒǩ .øÀƬÀöä özȑ Ž ãäÀÎϘèɍä ÙÛƯ ÒĦÀŧş .A òzŸɬä ȡɳ ǰϘÀǩ Û ÀƬȚţäş Ȝęzţä

ÀÀĦŧş R1 ɄDzŸǯöä ŌĒϘèɟä Ȑþ ȡɳ Ōɳ 30 Ž ÛǦĒùzǦȒɳ ǦφşàzɳÛȟ 0.35 ǦäÀę ãäØł ¦**Assay** ǦÊÀŌţä Non - ɄəÀɳŸöä Ùèzöä Ž gÀÀĦţä" ȷäzÀȝ ǨƠ ȣzòzɳ zȽ Àŧõ VS (ȯ/òzɳ 0.1) ŌÀøzŸõşƘǦöä Ȑþ òzŸĦɳ (ȯ/òzɳ 0.1) ŌÀøzŸõƘǦöä Ȑþ òzŸƬ ȡɳ Ōɳ 1 Ōõ .(142 ǦĦÀÔöä Û1 ÆŸÕä) A ǦŌÀÛöä Û"aqueous titration .$C_{10}H_{21}N_3O, C_6H_8O_7$ ȡɳ ɳŸɳ 39.14 ùzÀÒÀ VS

ØØØØØ

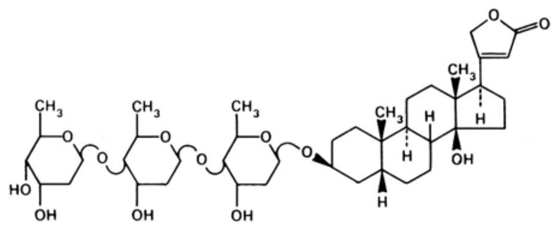
DIGITOXINUM

Digitoxin DzǐƨǀǋȋǕǏϙ

$C_{41}H_{64}O_{13}$ ¦**Molecular formula** ǦĒÀÂƨä ǦȣĒÔöä

765.0 ¦**Relative molecular mass** ǦĒǦÊÀöä ǦĒÀÂƨä ǦŸϘÒöä

Graphic formula: [illegible]



Chemical name: [illegible]

3*β*-[(*O*-2,6-Dideoxy-*β*-D-*ribo*-hexopyranosyl-(1→4)-*O*-2,6-**dideoxy**-*β*-D-*ribo*-hexopyranosyl-(1→4)-2,6-dideoxy-*β*-D-*ribo*-hexopyranosyl)-**oxy**]-14-hydroxy-5*β*-card-20(22)-enolide; CAS Reg. No. 71-63-6.

Description: [illegible].

Solubility: [illegible] (750~) [illegible] R [illegible].

Category: [illegible] Cardiotonic.

Storage: [illegible].

Additional information: [illegible].

REQUIREMENTS [illegible]

General requirement: [illegible] 95.0% [illegible] 105.0% [illegible] $C_{41}H_{64}O_{13}$ [illegible].

Identity tests: [illegible]

- [illegible] A [illegible] B [illegible] D [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Thin-layer chromatography" [illegible] (1 [illegible] 84) [illegible] Kieselguhr R1 [illegible] 10 [illegible] R [illegible] 90 [illegible]

[illegible] 15 [illegible] 5 [illegible] R [illegible]
[illegible] 5 [illegible]
50 [illegible] 2 [illegible]
[illegible] R [illegible] 4 R [illegible] 50 xylene R [illegible]
[illegible] RS [illegible] :(B) [illegible] :(A) [illegible] 3 [illegible]
[illegible] R [illegible] R [illegible] 50 [illegible]
[illegible] R [illegible] 5 [illegible] 1 [illegible] 10 [illegible]
[illegible] 20 [illegible] 115 [illegible] 12
750~) [illegible] 100 [illegible] R [illegible] 25 [illegible] 15 [illegible]
[illegible] tosylchloramide sodium R [illegible] 30 [illegible] 1 TS [illegible]
[illegible] 5 [illegible] 115 [illegible]
[illegible] A [illegible] 365) [illegible]
.B [illegible]

[illegible] 1 [illegible] TS [illegible] 750~) [illegible] 1 [illegible] 1 [illegible] :C
[illegible] VS [illegible] 1) [illegible] 1 TS [illegible]
.[illegible]

[illegible] 100 TS [illegible] 25) [illegible] 0.5 [illegible] 2 [illegible] 1 [illegible] :D
[illegible] TS [illegible] 1760~) [illegible] 1 [illegible] R [illegible]
[illegible]
.(allied glycosides [illegible])

R [illegible] 10 [illegible] **Specific optical rotation** [illegible]
. $[a]_D^{20\,°C} = +16.5 \text{ to } 18.5°$ [illegible]

.[illegible] 1.0 [illegible] **Sulfated ash** [illegible]

20 [illegible] 105 [illegible] **Loss on drying** [illegible]
.[illegible]

[illegible] 25 [illegible] R [illegible] 1 [illegible] 5 [illegible] **Gitoxin** [illegible]
[illegible] .R [illegible] TS [illegible] 250~) [illegible]

325 ... 1 ... 1 ...
... TS (ò/ȟ 250) ...
.(... 1 ... 2 ...) 0.28

25 ... R ... 0.05 ... **Assay** ...
... 5.0 ... R ... 100 ... 5.0 ...
... TS ... 15 ... 25 ...
... 1 ... 30 ... R ... 25
... 15 ... 490 ...
... $C_{41}H_{64}O_{13}$ ... R ... 25 ... TS ...
... RS

Additional requirements for Digitoxin for parenteral use

.(56 ... 4 ...) "*Parenteral preparations* ..." ...
... " ... **Bacterial endotoxins** ...
(... 30 ... 5 ...) "Test for bacterial endotoxins ...
... 111.0 ... RS ... 1 ...

ØØØØØ

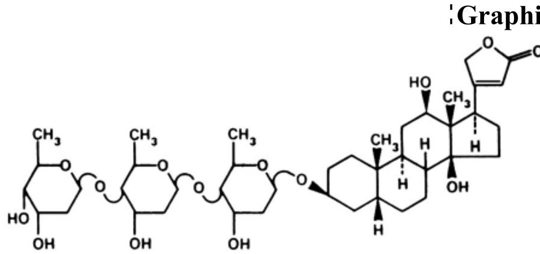
DIGOXINUM

Digoxin

$C_{41}H_{64}O_{14}$ ¦**Molecular formula**

781.0 ¦**Relative molecular mass**

¦**Graphic formula**



[illegible] **Chemical name**:

3β-[(O-2,6-Dideoxy-β-D-*ribo*-hexopyranosyl)-(1→4)-O-2,6-dideoxy-β-D-*ribo*-hexopyranosyl-(1→4)-2,6-dideoxy-β-D-*ribo*-hexopyranosyl)-oxy]-12β,14-dihydroxy-5β-card-20(22)-enolide; CAS Reg. No. 20830-75-5.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] TS (~750 [illegible]) [illegible] R [illegible].

[illegible] **Category**: [illegible] Cardiotonic.

[illegible] **Storage**: [illegible].

[illegible] **Additional information**: [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 95.0% [illegible] 103.0% [illegible] $C_{41}H_{64}O_{14}$ [illegible].

[illegible] **Identity tests**:

• [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Related substances" [illegible] A [illegible] B.

C: [illegible] 1 [illegible] 1 [illegible] TS (~750 [illegible]) [illegible] 1 [illegible] TS [illegible] 1 [illegible] (1 [illegible]) VS [illegible].

D: [illegible] 1 [illegible] 2 [illegible] 0.5 [illegible] TS (25 [illegible]) [illegible] 100 [illegible] 1 [illegible] TS (~1760 [illegible]) [illegible].

(allied glycosides.

Specific optical rotation: 10 ... $[a]_{546\ nm}^{20\ °C} = +13.6$ to $14.2°$.

Sulfated ash: 1.0 ...

Loss on drying: 0.6 ... 5 ... 10 ...

Gitoxin: 5 ... 1 ... TS (~675) ... 25 ... TS (~250) ... 352 ... 1 ... 1 ... R ... (~250 ... 0.22 ... 2 ... TS (1 ...).

Related substances: Thin-layer chromatography (1 ... 84) Kieselguhr R1 ... 10 ... R 90 ... R ... 5 ... 15 ... 5 ... 2 ... 4 R ... Xylene R 50 ... 50 ... 1 ... R ... 5.0 ... (A): R ... 1 ... 5.0 ... (B): 1 ... 0.25 ... RS ... (C): 1 ... RS ... 12 ... 115 ... 20 ... 15 ... 25 ... tosylchloramide sodium R 1 TS (~750) ... 100 R ... 5 ... 115 ... 30 ... A ... (365 ...

[illegible] C.

Assay [illegible] 0.05 [illegible] R [illegible] 25 [illegible] 5.0 [illegible] 100 [illegible] R. [illegible] 5.0 [illegible] 25 [illegible] 15 [illegible] TS [illegible] 25 [illegible] R. [illegible] 30 [illegible] 1 [illegible] 490 [illegible] 15 [illegible] 25 [illegible] TS [illegible] R. [illegible] $C_{41}H_{64}O_{14}$ [illegible] RS [illegible].

[illegible]

Additional requirements for Digoxin for parenteral use

[illegible] "*Parenteral preparations*" [illegible] 4 [illegible] 56).

Bacterial endotoxins [illegible] "Test for bacterial endotoxins" [illegible] 5 [illegible] 30 [illegible] 200.0 [illegible] RS [illegible] 1 [illegible].

[illegible]

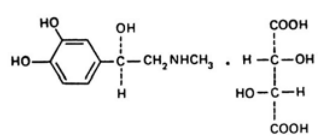
EPINEPHRINI HYDROGENOTARTARAS

Epinephrine hydrogen tartrate [illegible]

Molecular formula [illegible] $C_9H_{13}NO_3, C_4H_6O_6$ [illegible] $C_{13}H_{19}NO_9$

Relative molecular mass [illegible] 333.3

Graphic formula [illegible]



Chemical name [illegible]

(−)-(*R*)-3,4-Dihydroxy-*α*-[(methylamino)methyl]benzyl alcohol L-(+)-tartrate (1:1) (salt); (−)-(*R*)-4-[1-hydroxy-2-(methylamino)ethyl]-1,2-benzenediol[*R*-(*R**,*R**)]-2,3-dihydroxybutanedioate (1:1) (salt); (−)-*α*-3,4-dihydroxyphenyl-*β*-(methylamino)ethanol L-(+)-tartrate; CAS Reg. No. 51-42-3.

[illegible] Adrenalin [illegible] **Other name** [illegible]
[illegible]

[illegible] **Description** [illegible]

[illegible] **Solubility** [illegible] 3 [illegible] (750~ [illegible]) [illegible]
R [illegible] R [illegible].

Category [illegible] Sympathomimetic.

Storage [illegible].

Additional information [illegible]

REQUIREMENTS [illegible]

General requirement [illegible] 98.0% [illegible] 101.0% [illegible] $C_9H_{13}NO_3, C_4H_6O_6$ [illegible].

Identity tests [illegible]:

A: [illegible] 0.10 [illegible] 0.01 [illegible] VS [illegible] 230 [illegible] 350 [illegible] 280 [illegible] 1 [illegible] 0.8 [illegible].

B: [illegible] 10 [illegible] 1 [illegible] 10 [illegible] TS, 3.4 [illegible] 0.5 [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] 2 [illegible] VS (0.1 [illegible]) [illegible] 5 [illegible] levarterenol [illegible].

C: [illegible] B [illegible] "General identification tests [illegible]" [illegible] 1 [illegible] 123.

[illegible] 20 [illegible] 0.5 [illegible] **Specific optical rotation** [illegible]

(100~) [illegible] Sodium metabisulfite [illegible] 0.1 [illegible] C [illegible] 1 [illegible] TS [illegible] 5 TS (750~) [illegible] 5 [illegible] 2 [illegible] 5 [illegible] 0.6 [illegible] R [illegible] 0.5) [illegible] 20 [illegible] 3 [illegible] . $[a]_{D}^{20\ C^{\circ}} = -50 \text{ to } -53^{\circ}$ VS [illegible]

[illegible] 10 [illegible] 0.1 [illegible] **Clarity and colour of solution** [illegible]

[illegible] 1.0 [illegible] **Sulfated ash** [illegible]

0.6 [illegible] **Loss on drying** [illegible] 5.0 [illegible] 3 [illegible] R [illegible] 5 [illegible] 4.0 [illegible] 1 [illegible] **Adrenalone** [illegible] 2 [illegible] 0.2 [illegible] 310 [illegible] VS [illegible] 0.1) [illegible] 1 [illegible]

[illegible] 4 [illegible] 1 [illegible] 10 [illegible] **Levarterenol** [illegible] -4-[illegible]-1.2 [illegible] 1 [illegible] TS, 9.6 30 [illegible] sodium 1.2-naphthoquinone-4-sulfonate, TS [illegible] 5) [illegible] 15 [illegible] benzalkonium chloride TS1 [illegible] 0.2 [illegible] TS [illegible] 9.6 [illegible] R [illegible] 30 [illegible] 9.0 [illegible] R [illegible] 0.40 [illegible] 1 [illegible] R [illegible] (53 [illegible] 1 [illegible]) "Colour of liquids [illegible]"

[illegible] R1 [illegible] 50 [illegible] 0.3 [illegible] **Assay** [illegible] VS [illegible] 0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]

[illegible] 33.33 [illegible] 0.1) VS [illegible] $C_9H_{13}NO_3$, $C_4H_6O_6$.

[illegible]

Additional requirements for Epinephrine hydrogen tartrate for parenteral use

[illegible] "*Parenteral preparations*" [illegible] (56 [illegible] 4 [illegible]).

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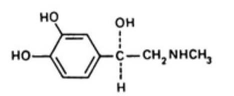
EPINEPHRINUM

Epinephrine [illegible]

[illegible] **Molecular formula**: $C_9H_{13}NO_3$

[illegible] **Relative molecular mass**: 183.2

[illegible] **Graphic formula**:



[illegible] **Chemical name**:

(–)-(*R*)-3,4-Dihydroxy-α-[(methylamino)methyl]benzyl alcohol; (–)-(*R*)-4-[1-hydroxy-2-(methylamino)ethyl]-1,2-benzenediol; (–)-α-3,4-dihydroxyphenyl-β-methylaminoethanol; CAS Reg. No. 51-43-4.

[illegible] **Other name**: [illegible] Adrenalin [illegible]

[illegible] **Description**: [illegible]

[illegible] **Solubility**: [illegible] (~750 [illegible]) [illegible] R [illegible] R [illegible] R [illegible]

[illegible] **Category**: Sympathomimetic.

[illegible] **Storage**: [illegible]

[illegible] **Additional information**: [illegible]

[illegible] %101.0 [illegible] %98.5 [illegible] **General requirement** [illegible] $C_9H_{13}NO_3$ [illegible].

Identity tests [illegible]:

A: [illegible] 0.030 [illegible] 0.01) [illegible] VS [illegible] 230 [illegible] 350 [illegible] 280 [illegible] 1 [illegible] 0.45 [illegible].

[illegible] 2 [illegible] 1 [illegible].)

B: [illegible] 10 [illegible] 10 [illegible] 0.01) [illegible] VS [illegible] 1 [illegible] 10 [illegible] 3.4 [illegible] TS [illegible] 0.5 [illegible] 2 [illegible] 0.1) [illegible] VS [illegible] 5 [illegible] levarterenol [illegible] 1 [illegible] 0.1) [illegible] VS [illegible].)

Specific optical rotation [illegible] 40 [illegible] 1) [illegible] VS [illegible] $[a]_{D}^{20\,°C} = -50 \text{ to } -53°$.

Sulfated ash [illegible] 1.0 [illegible].

Loss on drying [illegible] 0.6 [illegible] 5 [illegible] 18 [illegible] 10 [illegible].

pH value [illegible] 5.0 [illegible] 7.5 [illegible].

Adrenalone [illegible] 1 [illegible] 2.0 [illegible] 0.1) [illegible] VS [illegible] 310 [illegible] 0.2 ([illegible] 2 [illegible] 1 [illegible].)

Levarterenol [illegible] 5.0 [illegible] 1 [illegible] 5) [illegible] TS [illegible] 4 [illegible] 9.6 [illegible] TS [illegible] 1 [illegible] 1.2 [illegible] -4- [illegible] 5) sodium 1.2-naphthoquinone-4-sulfonate TS [illegible]

[illegible] 15 [illegible] TS1 [illegible] 0.2 [illegible] 30 [illegible] TS, 9.6 [illegible] R [illegible] 0.40 [illegible] 30 [illegible] 1 [illegible] R [illegible] 9.0 [illegible] R [illegible] (53 [illegible] 1 [illegible]) "Colour of liquids [illegible]"

[illegible] R1 [illegible] 30 [illegible] 0.35 [illegible] :**Assay** [illegible] Non - [illegible] VS (0.1 [illegible]) [illegible] (0.1 [illegible]) [illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) A [illegible] "aqueous titration [illegible] VS 18.32 [illegible] $C_9H_{13}NO_3$.

[illegible]

Additional requirements for Epinephrine for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]" [illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for bacterial endodoxins [illegible] 357.0 [illegible] RS [illegible] 1 [illegible].

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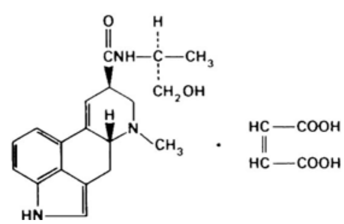
ERGOMETRINI HYDROGENOMALEAS

Ergometrine hydrogen maleate [illegible]

$C_{23}H_{27}N_3O_6$ [illegible] $C_{19}H_{23}N_3O_2, C_4H_4O_4$:**Molecular formula** [illegible]

441.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** ȖəǺȽȽǾǿä ǉèɍä

9,10-Didehydro-*N*-[(*S*)-2-hydroxy-1-methylethyl]-6-methylergoline-8*β*-carboxamide maleate (1:1) (salt); 9,10-didehydro-*N*-[(*S*)-2-hydroxy-1-methylethyl]-6-methylergoline-8*β*-carboxamide (*Z*)-2-butanedioate (1:1) salt; CAS Reg. No. 129-51-1.

.ǦȞəäÀǿä ƇÆʒ ÜǨȽǺǽ ÀǺǿǕ şǕ ȐȽǽǕ Ƀøźǽ ȧźȞȆȠ :**Description** Ȥòźǿä

Ž ɍş R Ƙǭɉä Ž ǺȄŸȶʒ ä̈ǻȿǽ Ƙȡ ǕTS (ȯ/ȟ 750~) ȯźǭǺǯǺȹäş ŏǺţä Ž ɈǺǽşǾǿä ǾȄŸȩ :**Solubility** ǦȄǭǺǽşǾǿä
.R ÿøźźşøźŸǾǿä

.Oxytocic ǥǻɍźŸǿ ǾȰźȄȟ :**Category** ǦǺǺǿä

ǾȒźɉäş ǕǿäźȚŸǿ ǈȄǭõ źǕ ɁŸʒ ǦǾŸ8ȵ ǦǺşǺǥ Ž ȸǺǺǭȵźȡøȹä ƘǅşøȄȽ ǧǺȄǿǺȵ ȘǺǥ Æƶ :**Storage** ȸǺÂǺǭǿä
.ǻøǺǽ ɈǺǾȵ Ž ɈȂǺȴ ɈǕş ŏźȒǿä ȸȵ ǦȽȶȚ ǕƘǅşǺǭǺǿä ǾǯȠ ǕǾǭǺǹ Ƀźǅ ȣŸȡ Ž

ôǺȞǭǿä ÆǺʒ ǺǺõäǻ ȸǺǺǭȵźȡøȹä ƘǅşøȄȽ ǧǺȄǿǺȵ Ɉźǿ ǴǴÔǺ :**Additional information** ǦȄźǺȓǕ ǧǺȵźŸȞȵ
äǺȄȡ Ž ɁøǭǴ ÆùǺǿä Ƀźƨä ȣŸ8Ÿǿ ôǺȞǭǿä ɁÆǿ ǺȄƶøÆǩ ȸǺǺǭȵźȡøȹä ƘǅşøȄȽ ǧǺȄǿǺȵ ǿøǺÆǭǩş .ŏźȒŸǿ
.ɁŸʒɉä ǥøäǺΣä ǧǺǅøǻ ÆǺʒ ţǺèǕ ǬǾǺǭǿä ɈźǾǺş ǕŏźȒǿä

REQUIREMENTS ƘǴǕǴǷǵǶ!ƒ

ɍş %98.0 ȸʒ ǾǬǺ ɍ Ǻȵ ɁŸʒ ȸǺǺǭȵźȡøȹä ƘǅşøȄȽ ǧǺȄǿǺȵ ɃźǭƠ :**General requirement** ÿǺȞǿä ÆŸǕǭţä
.ǦǺǺǾǿä ǥǺţä Ƃǖ ţźǅǺǿǺǽ ǦǽźȆȚ Ǖ$C_{19}H_{23}N_3O_2$, $C_4H_4O_4$ ȸȵ %101.0 ȸʒ ÆǺÂǺ

:**Identity tests** ȟǐǏǎǍǌ ǋǊǉǈǇǆ

.ȧøàǕ ȨǿǺǩ ǰǭǺǺ ǕŏǺţä ȸȵ Ǿȵ 5 Ž ȠŸȵ 15 äǻǾȴ :A
ǦȄȆȄəǺǿä ǦȞǾǦǿä Ȩźǿźǭǩ "Related alkaloid ǦŏǺȊţä ǧǺȄǭǺźŸǿä" ɈǺźǺʒ ǨƠ ǺǾǥɍ 8źòźţä øǺǦǭȵɍä ǺȚǭä :B
.C ȯźŸǂä ȸȵ ǦƟǺǺǿä ǬŸǩ ʒȵ ǥǺȊǿäş ǺȚȚţş ʒȩźţä Ž B ȯźŸǂä ȸȵ ǰǭǺǩ Ȗøǭǿä
ǾȄǯȄȵ ȖəǺǺǭ-4 ȯźŸȚ ȸȵ Ǿȵ 2 ȯźŸǂä äǻȽ ȸȵ Ǿȵ 1 Ƃǖ 8ǺȒȴ ǕŏǺţä ȸȵ Ǿȵ 20 Ž ȠŸȵ 2 äǻǾǺ :C
.ȨȵǺȡ ȧøàǕ Ɉźǿ ǰǭǺǺ ǕȨəǺȩǻ 5 ǦǺǿǺȩ øäǺǾǭèŸǿ ǿǺǭȴş TS1 ÆȽȽÆǿäÂøǺǽźȄȵǕ
.Ȥ ìǺǾǿä Ɉźǿ ɁìŸǭǺ ǕTS1 ÿşƎǿä ȯźŸȚ ȸȵ ǥǺǕȩ 1 8ǺȒȴş ŏǺţä ȸȵ Ǿȵ 1 Ž ȠŸȵ 2 äǻǾȴ :D
ţźǅǺǿǺǽ ÆȆȞȴş Ǿȵ/ȠŸȵ 10 ÂȄõǺǭǽ ȯźŸǂä ǾȶȞǭȆȴ :**Specific optical rotation** Ȗʒźǿä ɃǺǾǦǿä ǺǺşÆǭǿä
. $[a]_D^{20\,°C} = +50$ to $+ 56°$ ǕǦǺǺǾǿä ǥǺţä Ƃǖ

ȸȵ Ǿȵ 10 Ž ȟ 0.10 ÂȄõǺǭǽ ȯźŸǂä Ɉźǿ ʒȩì ÆǺÂǩ ɍ :**Clarity and colour of solution** ȯźŸǂä Ɉźǿş ŏǺǺò

[illegible] Yw3 [illegible] R [illegible]
.(53 [illegible] 1 [illegible]) "Colour of liquids [illegible]

[illegible] 80 [illegible] :**Loss on drying** [illegible]
[illegible] 20 [illegible] 5 [illegible] 0.6 [illegible]

[illegible] R [illegible] 10 [illegible] :**pH value** [illegible]
.5.0-3.0

[illegible] :**Related alkaloids** [illegible]
9 [illegible] R1 [illegible] .(84 [illegible] 1 [illegible]) "Thim-layer chromatography
[illegible] R [illegible] 1 R [illegible]
[illegible] TS (260~) [illegible] 25 [illegible]
[illegible] 4.0 [illegible] :(A) [illegible] 5 [illegible] 30
[illegible] 0.12 [illegible] :(C) [illegible] 1 [illegible] 0.12 [illegible] :(B) [illegible] 1 [illegible]
[illegible] 1 [illegible] RS [illegible]
[illegible] TS2 [illegible]-4 [illegible]
[illegible] A [illegible]
.B [illegible]

[illegible] 10 R1 [illegible] 20 [illegible] 0.20 [illegible] :**Assay** [illegible]
[illegible] VS (0.05) [illegible] R [illegible]
[illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]
$C_{19}H_{23}N_3O_2, C_4H_4O_4$ [illegible] 22.07 [illegible] VS (0.05) [illegible]

[illegible]

Additional requirements for Ergometrine hydrogen maleate for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]
[illegible] :**Bacterial endotoxins** [illegible]
[illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endodoxins [illegible]
[illegible] 1 [illegible] RS [illegible] 700.0 [illegible]

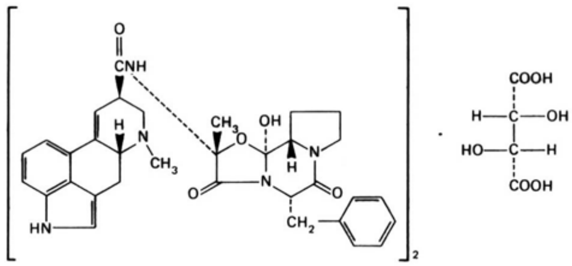
ERGOTAMINI TARTRAS

Ergotamine tartrate ǲĬĎǰǂǋǮþŬɛ lɛþƲþƲ

$C_{70}H_{76}N_{10}O_{16}$ ȿǕ Û($C_{33}H_{35}$ N_5O_5)$_2$, $C_4H_6O_6$ ¦**Molecular formula** ǦǼǞǞƨǟ Ǧ8ǼÔǚǟ

1313 ¦**Relative molecular mass** ǦǼǤÊǺǚǟ ǦǼǞǞƨǟ ǦŸǪȮǚǟ

¦**Graphic formula** ǦǼǿǞǼǤţǟ Ǧ8ǼÔǚǟ



¦**Chemical name** ȗǝǞǼŧǼȮǚǟ ɭèɍǟ

Ergotamine L-(+)-tartrate (2:1) (salt); 12′-hydroxy-2′-methyl-5′α-(phenylmethyl)ergotaman-3′,6′,18-trione[*R*-(*R,*R**)]-2,3-dihydroxybutanedioate (2:1) (salt); CAS Reg. No. 379-79-3.**

БǕ ãøǞȑ ȐǼǣǕ ȿǕ ɃǻǞɳǞǚǟ БǕ ãøǞȑ ȐǼǣǕ Ƀøȥǘǣ ȧȥǶÊɳ ȿǕ ɉȥǘǚǟ ǦȤǼǯ ğǟøȥǘǣ ¦**Description** Ȥȍȥǚǟ .ǦǶǝǟǞǚǟ ƇǼǯ ŰǞǞȍɉǟ

Ž ɍȿ ƘǬɉǟ Ž ǼŸţǯ ãǟȿǣ ƘȡŰŢS (ȯ/ȟ 750~) ȯȥǿǞǮǞɋǟ Žȿ ǒǞţǟ Ž ɉǞǣȿǾǚǟ ǴǼǶȉ ¦**Solubility** ǦǼǿǞǣȿǾǚǟ .R ȤǼǞȴǟ ȔǞǞǚǟ Ž ɍȿ R ȸǞÂøǞǦǚǟ

.Sympatholytic ɃǻȥǚǾ (ȍǞǵ) Ȑǵǟǻ ¦**Category** ǦǞǞǚǟ

8ɎȡŽ ŌȒȥɉǟȿ ÛǒǟȥȚǘǚ ɭǼǪõ ȥǛ ɁŸǯ ǦŌŸ8ɳ ǦǞȿǞǵ Ž ƙɳǞǩȥȡøɉǟ ğǟǞǚǞǚ ȘǞǵ Æƶ ¦**Storage** ȸǞÂǺǪǚǟ .ǻøǞǣ ɉǞȮɳ Ž ɉǞǺǩ ɉǕȿ ǒȥȒǚǟ ȸɳ ǦǼţȚ ÛƙǅȿǞǬǺǚǟ ŌǰɳÛŌȩǞǹ Ƀȥǅ

8Ɏ8Ÿǚ ȏǞǨǪǚǟ ʔǼǚ ǼǮƶøǼǩ ƙɳǞǩȥȡøɉǟ ğǟǞǚǞǚ ōǿǼǪǩ ¦**Additional information** ǦǼȥǞȑǕ ğǞɳȥŸǶɳ .ɁŸǯɉǟ ǵøǟǞƩǟ ğǞǅøǻ ǼǺǯ ţǞèǕ ÕȮǞǪǚǟ ɉȥȮǞȿ ÛǒȥȒǚǟ ãǞǼȡ Ž ɁøǪǵ ǼǚǞǚǟ Ƀȥƨǟ

REQUIREMENTS ƘǦǚǞƱƙǆ!ƒ

ȸǯ ǼǞÂǞ ɍȿ %98.0 ȸǯ ŌōǞ ɍ ǞɳɁŸǯ ƙɳǞǩȥȡøɉǟ ğǟǞǚǞǚ ɃȥǪƠ ¦**General requirement** ÿǞǨǚǟ ǼŸÛǪţǟ .ǦǞǞȮǟ ǵǻǞţǟ БǕ ţȥǅǞǚǞǣ ǦǣȥÊŢ Û($C_{33}H_{35}$ N_5O_5)$_2$, $C_4H_6O_6$ ȸɳ %101.0

Identity tests: [illegible]

A: [illegible] "Related alkaloids" [illegible] B [illegible] C.

B: [illegible] 1 [illegible] 5 [illegible] R [illegible] 5 [illegible] 1 [illegible] R [illegible] TS (1760) [illegible] 1 [illegible] TS (25) [illegible] 0.1 [illegible]

Specific optical rotation of ergotamine base: [illegible]

- [illegible]

[illegible] 0.35 [illegible] separator [illegible] 25 [illegible] 10 [illegible] TS (10) [illegible] 0.5 [illegible] R [illegible] 50 [illegible] R [illegible] 10 [illegible] 20 [illegible] 50 [illegible] 20 [illegible] 95 [illegible] 25.0 [illegible] 0.6 [illegible] 5 [illegible]

$[a]_D^{20C} = -150$ to $-160°$ [illegible]

Clarity and colour of solution: [illegible] 25 [illegible] R 50 [illegible] 10 [illegible] 20 [illegible] "Colour of liquids" [illegible] Yw2 [illegible] (53 [illegible]).

Loss on drying: [illegible] 95 [illegible] 0.6 [illegible] 5 [illegible] 50 [illegible]

Related alkaloids: [illegible] "Thim-layer chromatography" [illegible] (84 [illegible] R1 [illegible] 9 [illegible]

[illegible] R [illegible] 1ş R [illegible]

[illegible] TS (ὁ/ȟ 260~) [illegible] 25 [illegible]

[illegible] 5.0 [illegible] :(A) [illegible] 5 [illegible] 30

0.25 [illegible] :(C) [illegible] 1 [illegible] 0.25 [illegible] :(B) [illegible] 1 [illegible]

[illegible] 1 [illegible] RS [illegible]

[illegible] TS2 [illegible] -4 [illegible]

[illegible] A [illegible]

.B

[illegible] 6 [illegible] 15 [illegible] 0.3 [illegible] **Assay** [illegible]

[illegible] VS (ὁ/ὁ 0.05) [illegible] .R1 [illegible] 100ş R

.(142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible]

.($C_{33}H_{35}N_5O_5)_2$, $C_4H_6O_6$ [illegible] 32.83 [illegible] VS (ὁ/ὁ 0.05) [illegible] 1 [illegible]

ØØØØØ

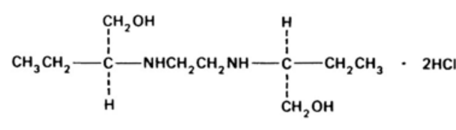
ETHAMBUTOLI HYDROCHLORIDUM

Ethambutol hydrochloride [illegible]

.$C_{10}H_{24}N_2O_2$, 2HCl **Molecular formula** [illegible]

277.2 **Relative molecular mass** [illegible]

Graphic formula [illegible]



Chemical name [illegible]

(+)-(*S*,*S*)-2,2′-(Ethylenediimino)di-1-butanol dihydrochloride; [*S*-(***R********,***R********)]-2,2′-(1,2-ethanediyldiimino)bis[1-butanol] dihydrochloride; CAS Reg. No. 1070-11-7.

[illegible] **Description** [illegible]

750~) [illegible] R [illegible] 850 [illegible] 1 [illegible] **Solubility** [illegible]

.R [illegible] RS [illegible]

.(tuberculostatic [illegible]) Antibacterial [illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]
.[illegible] $C_{10}H_{24}N_2O_2, 2HCl$ [illegible] %100.5 [illegible]

:**Identity tests** [illegible]

• .D [illegible] C [illegible] B [illegible] A [illegible] C [illegible]

[illegible] :A
[illegible] .(43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible]
reference spectrum [illegible] RS [illegible]
.[illegible]

[illegible] ."(*R*-Aminobutanol) ([illegible]-*R*)2" [illegible] :B
.C [illegible] B [illegible]

Genera; [illegible] B [illegible] 0.1 [illegible] :C
.(121 [illegible] 1 [illegible]) [illegible] "identification tests

.°[illegible] 200 [illegible] :D

:**Specific optical rotation** [illegible]

.$[a]_{D}^{20\,C^{\circ}} = +5.0 \text{ to } +7.0^{\circ}$ [illegible] 0.10 [illegible]

[illegible] 1.0 [illegible] :**Heavy metals** [illegible]
[illegible](127 [illegible] 1 [illegible]) [illegible] "Limit test for heavy metals [illegible]
.[illegible] 20 [illegible] (128 [illegible] 1 [illegible]) A [illegible]

.[illegible] 2.0 [illegible] :**Sulfated ash** [illegible]

5.0 [illegible] °[illegible] 105 [illegible] :**Loss on drying** [illegible]
.[illegible]

[illegible] **pH value** [illegible] 0.10 [illegible] 4.5-3.0.

[illegible] **2(*R*-Aminobutanol)** [illegible] "Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible]) R1 [illegible] R 7 [illegible] R 11 [illegible] R 1 [illegible] 2 [illegible] (~420 [illegible]) TS [illegible] 1 [illegible] 50 [illegible] (A): [illegible] R [illegible] 0.50 [illegible] 1 [illegible] (B): [illegible] 0.50 [illegible] R-2 [illegible] 1 [illegible] (C): [illegible] 1 [illegible] 105 [illegible] 5 [illegible] 90 [illegible] 5 [illegible] triketohydrindene\cadmium TS [illegible] C [illegible] A.

Assay [illegible] 0.3 [illegible] 100 [illegible] R1 [illegible] 10 [illegible] TS [illegible] (0.1 [illegible]) VS [illegible] "Non-aqueous titration [illegible] A [illegible] (142 [illegible] 1 [illegible]). [illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 13.86 [illegible] $C_{10}H_{24}N_2O_2$, 2HCl.

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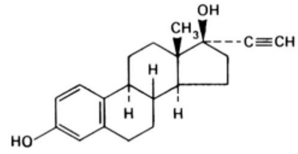
ETHINYLESTRADIOLUM

Ethinylestradiol [illegible]

$C_{20}H_{24}O_2$ **:Molecular formula** [illegible]

296.4 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



:Chemical name [illegible]

19-Nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol; 17-ethynyl-estra-1,3,5,(10)-triene-3,17β-diol; CAS Reg. No. 57-63-6.

Description : [illegible].

Solubility : [illegible] (750~ [illegible]) [illegible] R [illegible] R [illegible] R [illegible].

Category : [illegible].

Storage : [illegible].

Additional information : [illegible] poly morphic forms [illegible] 183 [illegible] 143 [illegible].

REQUIREMENTS [illegible]

General requirement : [illegible] %97.0 [illegible] %102.0 [illegible] $C_{20}H_{24}O_2$ [illegible].

Identity tests : [illegible]

• [illegible] A [illegible] B.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]). [illegible] reference spectrum [illegible] RS [illegible] B [illegible] 30 [illegible] R [illegible] 0.2 [illegible].

B: [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) Kieselguhr R1 [illegible] 1 [illegible] R 9 [illegible] R [illegible] 5 [illegible] 16 [illegible] 2 [illegible] 2 [illegible] 9 [illegible] R 1.0 [illegible] (B): [illegible] 1 [illegible] 1.0 [illegible] (A): [illegible] R [illegible] 1 R [illegible] 15 [illegible] 1 [illegible] RS [illegible].

120 ... 5-10 ... 120 ... 4-toluenesulfonic acid/ ethanol TS ... 15 ... (365) ... B.

Specific optical rotation ... 4.0 ... R ... $[a]_D^{20\,°C} = -27.0$ to $-30.0°$.

Loss on drying ... 105 ... 10 ...

Estrone ... Thin layer chromatography ... (84 ... 1 ... R1 ... 92 ... R ... 8 ... 0.5 ... 5 ... 1 ... 9 ... R ... 0.20 ... RS ... (A) ... 20 ... (B) ... 1 ... 1 ... TS ... 110 ... 10 ... (365) ... 110 ... 10 ... B ... A.

Assay ... 0.05 ... 100 ... 10.0 ... 50.0 ... 281 ... $C_{20}H_{24}O_2$ ... 1 ... RS ... 0.04 ± 72.

ØØØØØ

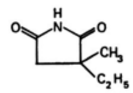
ETHOSUXIMIDUM

Ethosuximide

Molecular formula $C_7H_{11}NO_2$

141.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2-Ethyl-2-methylsuccinimide; 3-ethyl-3-methyl-2,5-pyrroli-
dinedione; CAS Reg. No. 77-67-8.

.[illegible] :**Description** [illegible]

.R [illegible] R [illegible] TS [illegible] 750~) [illegible] :**Solubility** [illegible]

.Anticonvulsant [illegible] :Category [illegible]

.[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

.[illegible]

REQUIREMENTS [illegible]

[illegible] %99.0 [illegible] :**General requirement** [illegible]

.[illegible] $C_7H_{11}NO_2$ [illegible] %105.0

:**Identity tests** [illegible]

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region (43 [illegible] 1 [illegible]). [illegible] *reference spectrum* [illegible] RS [illegible] TS [illegible] 750~) [illegible] 3 [illegible] (45 [illegible] 1 [illegible]). [illegible]

B: [illegible] 0.1 [illegible] 0.2 [illegible] R [illegible] 2 [illegible] 1760~) [illegible] TS

80~) ÿζÀåζÔöä ÆÊÕşøÆŁ ỏζŸĦŋ ɹƙŸĐł ÛöÀţä ȡŋ Ōŋ 5 ȣÀŘł ÛåĦĦö ÕÀǬł ÛĘəÀęå 5 ĝÆŋ °ÿ 140 ĝøäÀǵ ǦDZøÆæ .ȝüÀè ÀŘǹÜ ĘǟǔǩǰǬÀÀ ÜöÀţä ȡŋ ƘĠõ ȴDzǵ Ž ğäÀÛÕöä ȐĦæ ÆĿÔłş ÛTS (ỏ/ȟ

.°ÿ 46 ǦäǟÀę Û øÀƬÔφŗä ĝøäÀǵ ǦDZøå ŊŸǦǩ :C

ỏζŸȚ ȡŋ ğäÀÛę 3 ȣÀŘł ÛTS (ỏ/ȟ 750~) ỏζφÀǯÀɋä ȡŋ Ōŋ 10 Ž ȟ 1 āäØł :**Cyanides** ğäÆŒφÀŒÊöä ỏζŸȚ ȡŋ ğäÀÛÕöä ȐĦæş TS (ỏ/ȟ 80~) ÿζÀåζÔöä ÆÊÕşøÆŁ ỏζŸȚ ȡŋ Ōŋ 1ş TS (ỏ/ȟ 15) äşÀÀÂöä ğÀÀŸè ǰǬÀÀ ŗ ÜTS (ỏ/ȟ 100~) ȬÀøζÀŸÊöä Ȑƥ ỏζŸĦŋ ȎŧĦłş ȤÛŸæ üäÆł .TS (ỏ/ȟ 25) ȬÀÆÀÆΣä ÆÀøζŸõ .ǦÕŒęå 15 ỏŸǹ ȧøäÜ ɹζö şÜ öÀęøä ǦæÀèø

.ȟ/ŊŸŋ 5.0 ȡȝ ÆÀÂÀ ŗ :**Sulfated ash** ǨÀŸÊţä åÀŋÀöä

Determination of water by ÀÎŒζ ỏøÀõ ǦÕÀÀÛæ öÀţä ƙĦǩ" ɹäζÀȝ ǨƠ ȣζờζŋ ζŁ Àŧõ ȡĦǨł :**Water** öÀţä öÀţä ȜζǬȚ ÆÀÂÀ ŗ ÜĝåÀţä ȡŋ ȟ 1 ǦäǟÀę ÿäÆǺǬèÀæ Û(145 ǦĦÀÔöä Û1 ÆŸŎä) A ǦÕÀÀÛöä Û"Karl Fischer method .ȟ/ŊŸŋ 5.0 ȡȝ

ỏζŸĦŋ ÀÀÀĦłş åĦÀ .ĘəÀęå 5 ĝÆŋ ɄəÀŋ ÿÀƥ ȜŸȝ ǦÀζÆǬöÀæ öÀţä ȡŋ Ōŋ 50 Ž ȟ 5.0 āäØł :**Acidity** Ǧȓζŧ Σä ÆĦÛǬÀ ŗ ÜÀȞÎŧõ TS ỏζφÀǯÀÜ/ỏşÀÀÀõζŋşƎöä ĝÀŘȟ ỏζŸȚ ÿÆǺǬÊÀş ÛVS (ỏ/ỏζŋ 0.1) ÿζÀåζÔöä ÆÊÕşøÆŁ .(ÀŘǹÜ) ÀȞÎŧŸö ȜÛèζöä ǦÛÕÀöä ɹζö ȜŸȝ ỏζÔΣä ŌDZɉ Ōŋ 0.7 ȡŋ ÀǯõÜ

ǦÕŒęÀöä ǦÕǦÛöä āäÀÎǬèä" ɹäζÀȝ ǨƠ ȣζờζŋ ζŁ Àŧõ øÀǬǹŗä ĘĦÛł :**Related substances** ǦöÀÎţä åäζţä 9 ȡŋ ǰÀÂŋş ǦŸǿȣŋ ĝåÀŧõ R2 ÀÖŒŸŒÊöä ǦŋŸŁ ÿäÆǺǬèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸŎä) "Thin-layer chromatography ȡŋ ÀǬöşÀÒŋ 10 ǦĦŒÀÔöä ȜŸȝ ŸÔÀÀŋ ĘĦÛł .õÀĦǬŋ øζÛõ ÛR ɹζǬŒèɉä ȡŋ ÀŧDzǵ 1ş R ÿøζζşøζŸÒöä ȡŋ ÿζDzǵ :(B) ỏζŸǂäş Ōŋ 1 Ōõ Ž øÀǬǹŗä ĝåÀŋ ȡŋ ŊŸŋ 50 Ƀζʒ :(A) ỏζŸǂä ÛTS (ỏ/ȟ 750~) ỏζφÀǯÀɋä Ž ƙÀǬä ƙỏζŸȚ Ž ȤDzǬö õÀǬǩ āäÀÎǬèŗä ĝƘDzǵ ȡŋ ǦĦŒÀÔöä ţÂøφ ÆĦæş .Ōŋ 1 Ōõ Ž øÀǬǹŗä ĝåÀŋ ȡŋ ŊŸŋ 0.050 Ƀζʒ ÛA ỏζŸǂä ȡŋ ǰǬÀǩ ǦȞÕæ ǦÀÜ ɹζÒǩ ŗ .(ÀǬŋζφÀφ 254) ǦŒDzÊÀÀĠöä ȧζζ ǦĦìɉä Ž āäÀÎǬèŗä ÙÛƯ ȎĦÀÀş öäζTä .B ỏζŸǂä ȡŋ ǦƟÀÀöä ȬŸǩ ȡŋ ĝÆì ÀǯõÜ ÛǦŒÊŒəÀöä ǦȞÕĠöä öÀÀǯǬèÀæ

3 ȣÀŘł ÛR ÆŒŋÀŋøζζ ŌŒǯŒŋ ɄəÀÀǬ ȡŋ Ōŋ 30 Ž ÛǦŒüζĠŘŋ ǦφşäζŊ Ûȟ0.28 ǦäǟÀę āäØł :**Assay** ǦÊÀÀÕţä (ỏ/ỏζŋ 0.1) ÿζŒφζŋÜ ŌŒǩζæ ɃȝÀäø ÆÊÕşøÆŁ ỏζŸĦŋ ÀÀÀĦłş azo violet TS şäǿä ǦŒDzÊÀÀæ ỏζŸȚ ȡŋ ğäÀÛę Non-aqueous ɄəÀŋŸöä ÙèζöäŽ ĝÀÀȞţä" ɹäζÀȝ ǨƠ ȣζờζŋ ζŁ Àŧõ ÛöÀęøÂöä ǦŒəÀƬÀöä ǦÛÕÀöä ȜøǬǵ VS 0.1) ÿζŒφζŋÜ ŌŒǩζæ ɃȝÀäø ÆÊÕşøÆŁ ỏζŸȚ ȡŋ Ōŋ 1 Ōõ .(142 ǦĦÀÔöä Û1ÆŸŎä) B ǦÕÀÀÛöä Û"titration .$C_7H_{11}NO_2$ ȡŋ ŊŸŋ 14.12 ȕζÀÒÀ VS(ỏ/ỏζŋ

FERROSI SULFAS

Ferrous sulfate [illegible]

exsiccated [illegible] **Ferrous sulfate** [illegible]

Ferrous sulfate heptahydrate [illegible]

[illegible] $FeSO_4,7H_2O$ [illegible] $FeSO_4,nH_2O$:**Molecular formula** [illegible] .(heptahydrate

[illegible] 278.0 [illegible] 151.9 :**Relative molecular mass** [illegible] .(heptahydrate

:**Chemical name** [illegible]

Iron(2+) sulfate (1:1); CAS Reg No. 77720-78-7 (anhydrous) ([illegible])

Iron (2+)sulfate (1:1) ; heptahydrate; CAS Reg. No. 7782-63-0 (heptahydrate [illegible])

[illegible] :**Description** [illegible] heptahydrate [illegible]

[illegible] :**Solubility** [illegible] .TS [illegible] 750~) [illegible] heptahydrate [illegible] .TS [illegible] 750~) [illegible]

.([illegible]) Haemopoietic [illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

[illegible] :**Labelling** [illegible] .heptahydrate [illegible]

[illegible] :**Additional information** [illegible] 40 [illegible]

[illegible] %80.0 [illegible] **General requirement** [illegible] %105.0 [illegible] %98.0 [illegible] $FeSO_4$ [illegible] %90.0 [illegible] .$FeSO_4$,$7H_2O$ [illegible]

Identity tests [illegible]:

A: [illegible] 20 [illegible] General [illegible] "identification tests [illegible] (121 [illegible] 1 [illegible]).

B: [illegible] 20 [illegible] A [illegible] General [illegible] "identification tests [illegible] (123 [illegible] 1 [illegible]).

Heavy metals [illegible] 1.0 [illegible] 10 [illegible] 2 [illegible] TS (~250[illegible]) [illegible] TS (~330[illegible]) [illegible] 5 [illegible] 20 [illegible] TS (~250[illegible]) [illegible] 3 [illegible] 20 [illegible] 100 [illegible] R [illegible] 1 [illegible] TS (~250[illegible]) [illegible] 50 [illegible] 25 [illegible] TS [illegible] "Limit test for heavy metals [illegible] A [illegible] (128 [illegible] 1 [illegible]) [illegible] 2 [illegible] 50 [illegible].

Alkaline salts [illegible] 1 [illegible] 10 [illegible] TS (~1000[illegible]) [illegible] TS (~100[illegible]) [illegible] 1.0 [illegible].

Arsenic [illegible] 3.3 [illegible] 25 [illegible] "Limit test for arsenic [illegible] (130 [illegible] 1 [illegible]) [illegible] 3 [illegible].

Insoluble matter [illegible] 1.0 [illegible] 10 [illegible] 105 [illegible] 5.0 [illegible].

.4.0-3.0 ÛṎŋ/ȟ 0.05 ÂĿõÂǪ ȯɀŸǂā ǒÅŁÅæ ŊŸǤA ¦**pH value** ǒÅŁÅǤöā Ǥŧǿȩ

Ō̈ŋ 30 ȸŋ ǰAÂŋ Ž ÛǤĿùɀǤȒŋ Ǥǫşàɀŋ Ûȟ 0.3 ǤæāÅȩ ā āØł ÛǤÅǣǱŧā àşǼAǼΣā ğÅAŸè ŌǱɉ ¦**Assay** ǤÊAÅÕţā

0.1) ÿɀAƘÊöā ÿɀĿǫɀŋÛ ğÅAŸè ȯɀŸȞŋ ÄÅÅĦŧş TS (ȯ/ȟ 100~) ŌAøɀÅŸÊöā ȐƥȯɀŸƮ ȸŋ Ō̈ŋ 20ş ǒÅţā ȸŋ

o-phenanthroline TS ƙǒşÄǯǫÅĿɀɀǭøşÛ ȯɀŸƮ ȸŋ ǥÀÛȩ 2 ÿǼÁǪÊŀş ÛCeric ammonium sulfate VS (ȯ/ȯɀŋ

.$FeSO_4$ ȸŋ ŊŸŋ 15.19 ùɀÅÒA VS (ȯ/ȯɀŋ 0.1) ÿɀAƘÊöā ÿɀĿǫɀŋÛ ğÅAŸè ȯɀŸƮ ȸŋ Ō̈ŋ 1 Ōõ ÛÄĦÎŧõ

Ō̈ŋ 150 ȸŋ ǰAÂŋ Ž R ÿɀAåɀÔöā ƙǱşøǼĿ ğÅǫɀæÄõ ȸŋ ȟ 2.5 ā āØł ǒÅţā ǤĿȝÅǤè àşǼAǼΣā ğÅAŸè ŌǱɉş

1440~) ŌAøɀÅÊÄöā ȐƥȯɀŸƮ ȸŋ Ō̈ŋ 5.0ş TS (ȯ/ȟ 1760~) ŌAøɀÅŸÊöā ȐƥȯɀŸƮ ȸŋ Ō̈ŋ 10.0 ş ǒÅţā ȸŋ

ȷÅæşØöā ŋǪA ÅŋǼAȝş ÛǤĿùɀǤȒŋ Ǥǫşàɀŋ ÛøÅǤǪǹɍā ǥåÅŋ ȸŋ ȟ 0.5 ǤæāÅȩ ȣÅȒŀ ÛȷāøǩÅöā Ȥɇɀ̈ǪA ÅŋǼAȝş .TS (ȯ/ȟ

ȯɀŸƮ ȸŋ ǥÀÛȩ 2 ÿǼÁǪÊAş Ûceric ammonium sulfate VS (ȯ/ȯɀŋ 0.1~) ÿɀAƘÊöā ÿɀĿǫɀŋÛ ğÅAŸè ȯɀŸȞŋ ÄÅÅĦŀ

VS (ȯ/ȯɀŋ 0.1~) ÿɀAƘÊöā ÿɀĿǫɀŋÛ ğÅAŸè ȯɀŸƮ ȸŋ Ō̈ŋ 1 Ōõ .ÄĦÎŧõ *o*-phenanthroline TS ƙǒşÄǯǫÅĿɀɀǭøşÛ

.$FeSO_4$, $7H_2O$ ȸŋ ŊŸŋ 27.80 ùɀÅÒA

ØØØØØ

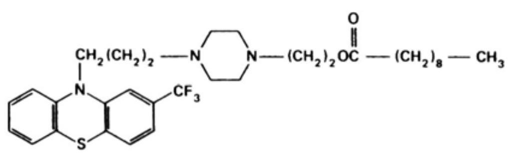
FLUPHENAZINI DECANOAS

Fluphenazine decanoate ǱǏŘǻǏɀǸǂƧƐ ƖƐǸǼƑƖǏƍ

$C_{32}H_{44}\ F_3N_3O_2S$ ¦**Molecular formula** ǤĿÅAÂƨā Ǥ8ĿÔöā

591.8 ¦**Relative molecular mass** ǤĿǤÊAöā ǤĿÅAÂƨā ǤŸǪÒöā

¦**Graphic formula** ǤĿǫÅĿǤţā Ǥ8ĿÔöā



¦**Chemical name** ȸəÅĿŧĿÒöā ƪèɍā

4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazineethanol decanoate (ester); 4-[3-[2-(trifluoromethyl)-10*H*-phenothiazin-10-yl]propyl]-1-piperazineethanol decanoate (ester); CAS Reg. No. 5002-47-1.

ȼǤÎǩ ÛǤĿƮ8ŀ ÛǤĦəāÅöā ÜÄÅòÛ Ƀøɀæ ÛȸøǪAà ǼŸƂ şÛ ǼĝÅĭ ÄÅòÛ ȷɀŸæ ǯÂö ŌəÅè ¦**Description** Ȥòɀöā

.ÄǪèǫā

Miscibility: [illegible] R [illegible] R [illegible] R.

Category: [illegible] Neuroleptic.

Storage: [illegible].

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %98.5 [illegible] %101.5 [illegible] $C_{32}H_{44}F_3N_3O_2S$ [illegible].

Identity tests [illegible]:

A: [illegible] "Spectrophotometry in the infrared region [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible]) [illegible] R2 [illegible] 5 [illegible] R *n*-tetradecane 95 [illegible] R [illegible] 5 [illegible] 1 [illegible] 10 [illegible] R [illegible] 90 [illegible] 20 [illegible] (A): [illegible] 1 [illegible] (~750 [illegible]) TS [illegible] R [illegible] 20 [illegible] (B): [illegible] RS [illegible] 1 [illegible] (254 [illegible]) [illegible] A [illegible] B.

C: [illegible] 5 [illegible] 2 [illegible] (~1760 [illegible]) TS [illegible] 5 [illegible].

Sulfated ash [illegible]: [illegible] 2.0 [illegible].

[illegible] 60 [illegible] **Loss on drying** [illegible] 0.6 [illegible] 5 [illegible] 10 [illegible].

[illegible] **Related substances** [illegible] "Thin-layer chromatography [illegible] (84 [illegible] R2 [illegible] 80 [illegible] TS [illegible] 260~) [illegible] 5 R [illegible] 30 R [illegible] 25 [illegible] (A) [illegible] 20 [illegible] 1 [illegible] RS [illegible] 0.25 [illegible] (B) [illegible] 1 [illegible] TS [illegible] 635~) [illegible] 254) [illegible] A [illegible] B.

[illegible] **Assay** [illegible] 0.6 [illegible] 30 [illegible] R1 [illegible] Non - [illegible] VS (0.1 [illegible]) [illegible] (0.1 [illegible]) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "aqueous titration [illegible] VS [illegible] 25.59 [illegible] $C_{32}H_{44}F_3N_3O_2S$.

[illegible]

Additional requirement for Fluphenazine for parenteral use

[illegible] "*Parenteral preparations* [illegible] (56 [illegible] 4 [illegible]).

[illegible]

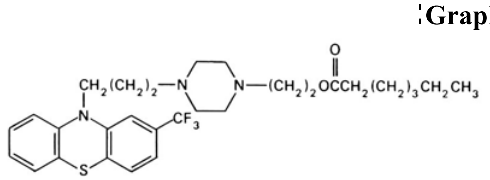
FLUPHENAZINI ENANTAS

Fluphenazine enantate [illegible]

$C_{29}H_{38}F_3N_3O_2S$ **Molecular formula** [illegible]

549.7 **Relative molecular mass** [illegible]

Graphic formula [illegible]



[illegible] **:Chemical name**

4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazineethanol decanoate (ester); 4-[3-[2-(trifluoromethyl)-10*H*-phenothiazin-10-yl]propyl]-1-piperazineethanol decanoate (ester); CAS Reg. No. 5002-47-1.

[illegible] **:Description** [illegible]

[illegible] R [illegible] R [illegible] R [illegible] **:Miscibility** [illegible]

.Neuroleptic [illegible] **:Category** [illegible]

[illegible] **:Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.5 [illegible] **:General requirement** [illegible]
$C_{29}H_{38}F_3N_3O_2S$ [illegible] %101.5

:Identity tests [illegible]

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) [illegible] R2 [illegible] 5 [illegible] R *n*-tetradecane 95 [illegible] R [illegible] 5 [illegible] 90 [illegible] 10 R [illegible] 1 [illegible] (A) [illegible] 20 [illegible] 1 [illegible] TS (750~) [illegible] (B) [illegible] 20 [illegible] RS [illegible] 1 [illegible] (254) [illegible] A [illegible] B.

[illegible] 5 [illegible] TS (ó/ȟ 1760~) [illegible] 2 [illegible] 5 [illegible] :C [illegible]

[illegible] **Sulfated ash**: [illegible] 2.0 [illegible]

[illegible] **Loss on drying**: [illegible] 60 [illegible] 0.6 [illegible] 5 [illegible] 10 [illegible]

[illegible] **Related substances**: [illegible] 80 [illegible] R2 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] TS (ó/ȟ260~) [illegible] 5 R [illegible] 30 R [illegible] 25 [illegible] :(A) [illegible] R [illegible] 20 [illegible] 1 [illegible] RS [illegible] 0.25 [illegible] :(B) [illegible] 1 [illegible] TS (ó/ȟ 635~) [illegible] (254 [illegible]) [illegible] A [illegible] B [illegible]

[illegible] **Assay**: [illegible] 0.55 [illegible] 30 [illegible] R1 [illegible] Non - [illegible] VS (ó/ó 0.1) [illegible] (ó/ó 0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "aqueous titration [illegible] VS [illegible] 27.49 [illegible] $C_{29}H_{38}F_3N_3O_2S$.

[illegible]

Additional requirement for Fluphenazine enantate for parenteral use

[illegible] "*Parenteral preparations* [illegible] (56 [illegible] 4 [illegible]).

ØØØØØ

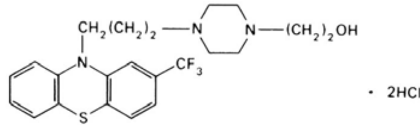
FLUPHENAZINI HYDROCHLORIDUM

Fluphenazin hydrochlorid [illegible]

Molecular formula: $C_{22}H_{26}F_3N_3OS,2HCl$ [illegible]

Relative molecular mass: 510.4 [illegible]

Graphic formula [illegible]:



Chemical name [illegible]:

4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazineethanol dihydrochloride; 4-[3-[2-(trifluoromethyl)-10H-phenothiazin-10-yl]propyl]-1-piperazineethanol dihydrochloride; CAS Reg. No. 146-56-5.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] 10 [illegible] (ό/ĥ750~) [illegible] TS [illegible] R [illegible].

Category [illegible]: [illegible] Neuroleptic.

Storage [illegible]: [illegible].

Additional information [illegible]: [illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] %98.5 [illegible] %101.5 [illegible] $C_{22}H_{26}F_3N_3OS,2HCl$ [illegible].

Identity tests [illegible]:

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]). [illegible] *reference spectrum* [illegible] RS [illegible].

B: [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) [illegible] Kieselguhr R1 [illegible] 15 [illegible] R [illegible] 5 [illegible] -2 [illegible] R 180 [illegible] R [illegible] 5 [illegible].

R1 ... 100 ... R ... 2 ... .R ... 2- ...

RS ... 2.0 ... :(B) ... 1 ... 2.0 ... :(A)

... 1 ... 365) ...

A ... TS ... .B ...

:C ... 5 ... 5 ... (1760~) ... TS ...

:D ... 0.5 ... TS ... 5 ... 3 ... 5 ...

:E ... 0.05 ... B ... General identification tests" ... (121 ...).

Sulfated ash ... 2.0 ...

Loss on drying ... 105 ... 10 ...

Related substances ... "Thin-layer chromatography (84 ...) ... R2 ... 80 ... 30 ... R ... 5 ... R ... (260~) ... TS ... 10 ... 1 ... 0.10 ... :(B) ... 1 ... 10 ... :(A) ... 254) ... A ... .B ...

Assay ... 0.5 ... 30 ... R1 ... 10 ...

Ȣǽǹǽǋ ǽŁ ǻƭõ ÛVS (ǿ/ǿǽǋ 0.1) ǬǺǿǽǛõƘǤä Ȑƭש ǺǺǻǶƙŞ TS ǬƐǪƐèǰä Ȑþ/ĘǤǝÂä ğǻǪƐèǛ ǿǽǛƮ ȸǋ Ǭǋ Ǭǋ 1 Ǭõ .(142 ǦǶǻÔä Û1 ǼǛǑä) A ǦǬǺÛä Û"Non-aqueous titration ȹǝǻǋƳä Ǜèǽä Ž ğǺǺǶƫä" ȷäǽǺȝ ǨƠ

.$C_{22}H_{26}F_3N_3OS,2HCl$ ȸǋ ǊǛǋ 25.52 ǜǽǻǑǺ VS (ǿ/ǿǽǋ 0.1) ǬǺǿǽǛõƘǤä Ȑþ ǿǽǛƮ ȸǋ

ØØØØØ

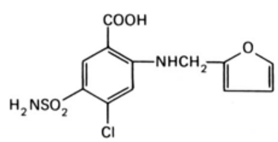
FUROSEMIDUM

Furosemide ǭǏǄǐ ƨǸþǸǯ

$C_{12}H_{11}ClN_2O_5S$ ¦**Molecular formula** ǦƐǺǺÂƨä Ǧ8ƐÔä

330.8 ¦**Relative molecular mass** ǦƐǤÊǺä ǦƐǺǺÂƨä ǦǛǪǑä

¦**Graphic formula** ǦƐǬǻƐǤƫä Ǧ8ƐÔä



¦**Chemical name** ȹǝǻƐƭƐǑä ǈèƦä

4-Chloro-*N*-furfuryl-5-sulfamoylanthranilic acid; 5-(aminosulfonyl)-4-chloro-2-[(2-furanylmethyl)amino]benzoic acid; CAS Reg. No. 54-31-9.

.ǦǶǝǻǺǑä ǢǼȝ ǛǶǤǺǑǨ ȐƐǛ ş ȐƐǛ ȹǿǽǛä ǻǽǶÊǋ ¦**Description** Ȥǹǽä

ǛTS (ǿ/ȟ750~) ǿǽǭǻǮǺǫä ǿǽǛƮ ȸǋ ǒǺǅ 75 Ž ǻäşä Û ǒǻƫä Ž ǻƐǛƭȝ ǻäşä Ƙƌ ¦**Solubility** ǦƐǭǻäşǾä

.R ȳøǽǽşǿǽǛǑä Ž ǻǼǅ ȷǻäşǾä ǴƐǶì ǛR ƘǬǰä Ž ȷǻäşǾä ǴƐǶì

.Diuretic ǿǽǤǛ ǿǼǋ ¦**Category** ǦǺǻä

.ǿǽȒä ȸǋ ǦƐƭƮ ÛǻǼƐǅ ǦǬǛ8ǋ ǦǺşǻǵ Ž ǼƐƭƐèşǿǽǺä ȘǻǵǼƶ ¦**Storage** ȸǺÂǺǪä

REQUIREMENTS ƘǦǶǷƱƘǆ!ƒ

%101.5 ȸȝ ǼǺÂǺ Ʀş %98.0 ȸȝ ǬǑǺ Ʀ ǻǋ ƻǛȝ ǼƐƭƐèşǿǽǺä ǺǽǪȜ ¦**General requirement** ȳǻǶä ǼǛÛǪƫä

.ǦǺǻǑä ǵǻǻƫä ǺǛ ƫǽǅǺǑǻǼ ǦǼǽÊƮ Û$C_{12}H_{11}ClN_2O_5S$ ȸǋ

¦**Identity tests** ƕǐǸǸǁǁ ƪ ƐþƑǦƗǪƐ

• ȸǾǽ ĘƐǤÛǨ ǻǋǛ ǿǻǤǪǹƦä A ǢǻǺǻǋ ş ǛǶǤǪǹƦä B ǿǽǬǻǤǪǹƦä B şC.

[illegible] :A [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] *reference spectrum* [illegible] RS [illegible]

[illegible] 10 [illegible] 1 [illegible] .R [illegible] 10 [illegible] 5 [illegible] :B [illegible] 15 [illegible] TS [illegible] 70~) [illegible] 1) [illegible] 5 VS [illegible] 1) [illegible] 15 [illegible] 1 [illegible] .TS [illegible] 25) [illegible] 2 [illegible] 3 [illegible] *N*-(1-naphthyl)ethylene-diamine hydrochloride TS [illegible] 5) [illegible] (-1)-*N* [illegible]

[illegible] 2 [illegible] TS [illegible] 750~) [illegible] 2.5 [illegible] 25 [illegible] :C [illegible] 4-dimethyl amino benz aldehyde TS1 [illegible] -4 [illegible]

[illegible] 1.0 [illegible] :**Heavy metals** [illegible] (127 [illegible] 1 [illegible]) 3 [illegible] "Limit test for heavy metals [illegible]" [illegible] (128 [illegible] 1 [illegible]) A [illegible] 20 [illegible]

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

[illegible] 105 [illegible] :**Loss on drying** [illegible] 5.0 [illegible]

[illegible] 25 [illegible] 0.1 [illegible] :**4-Chloro-5-Sulfamoylanthranilic acid** [illegible] -5- [illegible] -4 [illegible] 1 [illegible] 12 R [illegible] 3 [illegible] 1 [illegible] .R [illegible] TS [illegible] 10) [illegible] 0.5 [illegible] .VS [illegible] 1) [illegible] TS [illegible] 5) [illegible] (-1)-*N* [illegible] 1 [illegible] 5 [illegible] 25 [illegible] *N*-(1-naphthyl) ethylene diamine hydrochloride [illegible] blank [illegible] 530 [illegible] 1 [illegible] R [illegible] 3 R [illegible] 1 [illegible] -5- [illegible] -4 [illegible] %0.3 [illegible] 0.12 [illegible] 2 [illegible] (4-chloro-5 sulfamoylanthranilic acid

[illegible] 1 [illegible]

[illegible] **Related substances** [illegible] "Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible] R1 [illegible] 1 [illegible]

R [illegible]-2 [illegible] 3 [illegible] R [illegible] 3 xylene R [illegible] 1 [illegible] R [illegible]

[illegible] 5 [illegible] TS ([illegible] 260~) [illegible] 2 [illegible]

[illegible] 0.30 [illegible] :(B) [illegible] 1 [illegible] 20 [illegible] :(A) [illegible] R [illegible]

[illegible] 1 [illegible]

[illegible] A [illegible] 365) [illegible]

[illegible] B [illegible].

[illegible] 3 [illegible] R [illegible] 40 [illegible] 0.3 [illegible] **Assay** [illegible]

VS ([illegible] 0.1) [illegible] TS [illegible]

[illegible] 1 [illegible]

$C_{12}H_{11}ClN_2O_5S$ [illegible] 33.08 [illegible] VS ([illegible] 0.1) [illegible]

[illegible]

Additional requirement for Furosemide for parenteral use

(56 [illegible] 4 [illegible]) "*parenteral preparations* [illegible]

[illegible] **Bacterial endotoxins** [illegible]

[illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible]

[illegible] 1 [illegible] RS [illegible] 3.6 [illegible]

[illegible]

GLUCOSUM

Glucose [illegible]

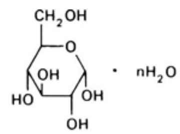
Glucose, anhydrus [illegible]

Glucose monohydrate [illegible]

([illegible]) $C_6H_{12}O_6, H_2O$ ([illegible]) $C_6H_{12}O_6$ **Molecular formula** [illegible]

([illegible]) 198.2 ([illegible]) 180.2 **Relative molecular mass** [illegible]

Graphic formula : [illegible]



n = 0 (anhydrous)
n = 1 (monohydrate)

Chemical name : [illegible]

α-D-Glucopyranose; CAS Reg. No. 492-62-6 (anhydrous).
α-D-Glucopyranose monohydrate; CAS Reg. No. 14431-43-7 (monohydrate).

Other name : [illegible] Dextrose.

Description : [illegible].

Solubility : [illegible] 1 [illegible] (~750 g/l) TS [illegible] (~750 g/l) TS.

Category : [illegible] Nutrient [illegible] fluid replenisher.

Storage : [illegible].

Labelling : [illegible] "For oral use only".

Additional information : [illegible].

REQUIREMENTS [illegible]

General requirement : [illegible] 99.0% [illegible] 101.5% [illegible] $C_6H_{12}O_6$ [illegible].

Identity tests : [illegible]

A: [illegible].

B: [illegible] 0.05 g/ml [illegible] 5 ml [illegible] potassio-cupric tatrate TS [illegible].

Specific optical rotation : [illegible] 10.0 g [illegible] 50 ml [illegible] 0.2 ml [illegible]

.ǦŐĔęǻ 30 ǥǼŋ øǻÀŎǪèŸǒ ōǺǪŀş Ōŋ 100 øǼŎǽ ǈDzǵ ǒÅÛȝɋ ǒǺţǻ ȸŋ ǦĔźǺō ǦĔŧōş TS (ȯ/ȟ 100~) ǺĔφźŋɉǻ ȯźŸŢ
. $[a]_{D}^{20°C}$ = +52.5 to + 53.0° ÜǦĔǝǺŋŸǒǻ ǥǻǺţǻ ƁÜ ţźDZÀǒǺǽ ǦDzĔǪǺǒǻ ǼĔÊȞǺŀ

ǨƠ Ȣźòźŋ źȽ Ǻŧō øǺǪǹɍǻ ȯźŸŢ ƘȒȞǪǒ ȟ 1.0 ŌŧȞǪÊǺ :**Heavy metals** ǦŸĔŐǯǒǻ (ǧǻÂŸǺǒǻ) ȷǻǺȞţǻ
Ü(127 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) 1 ǒǻÀDZɋǻ Û"Limit test for heavy metals ǦŸĔŐǯǒǻ ȷǻǺȞţǻ ŌDZɉ ɃǼΣǻ øǺǪǹɍǻ" ȷǻźǺȝ
.ȟ/ÿǻÀɖşÀŎŋ 5 ȸȝ ǼǺÂǺ ɍ Ü(128 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) A ǦŐǺÀÛǒǻ Ȩźş ǦŸĔŐǯǒǻ ȷǻǺȞţǻ ɁźǪŢ ȸĔȞǺŀ

ǨƠ Ȣźòźŋ źȽ Ǻŧō ŌŧȞǒǻ ŌŧȮǪÊǺş ǒǺţǻ ȸŋ Ōŋ 35 Ž ȟ 10 ÂĔōÀǪǽ ȯźŸɉǻ ŌŧȞǪÊǺŀ :**Arsenic** ǸĔφøÂǒǻ
.ȟ/ÿǻÀɖşÀŎŋ 1 ȸȝ ǼǺÂǺ ɍ Ü(130 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) "Limit test for arsenic ǸĔφøÂǒǻ ŌDZɉ ɃǼΣǻ øǺǪǹɍǻ" ȷǻźǺȝ

Ōŋ 20ş TS (ȯ/ȟ130~) ŌǺÀǪǺǒǻ Ȓþ ȯźŸŢ ȸŋ Ōŋ 2 ȸŋ ǰǺÂŋ Ž ȟ 1.25 ǡǻØǺ :**Chlorides** ǧǻǼǺøźŸŎǒǻ
"Limit test for chlorides ǧǻǼǺøźŸŎǒǻ ŌDZɉ ɃǼΣǻ øǺǪǹɍǻ" ȷǻźǺȝ ǨƠ Ȣźòźŋ źȽ Ǻŧō ŌŧȞǒǻ ɁÀDzǺş ǒǺţǻ ȸŋ
.ȟ/ƞŸŋ 0.2 ȸȝ ǧǻǼǺøźŸŎǒǻ ɁźǪŢ ǼǺÂǺ ɍ Ü(121 ǦȞǺÔǒǻ Û1 ǼŸŎǻ)

ɃǼΣǻ øǺǪǹɍǻ" ȷǻźǺȝ ǨƠ Ȣźòźŋ źȽ Ǻŧō ŌŧȞǒǻ ɁÀDzǺş ǒǺţǻ ȸŋ Ōŋ 20 Ž 2.5 ǡǻØǺ :**Sulfates** ǧǺÂŸÊǒǻ
.ȟ/ƞŸŋ 0.2 ȸȝ ǧǺÂŸÊǒǻ ɁźǪŢ ǼǺÂǺ ɍ Ü(125 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) "Limit test for sulfates ǧǺÂŸÊǒǻ ŌDZɉ

ȸŋ Ōŋ 30 ȝŋ ȟ 1 ɁŸȢǺ :**Less-solubIe sugars and dextrins** ǺφǺǽşǽ Ōęɉǻ ǧǺÂǺÀǪÊōǼǒǻş ǧǺÂǺȮÊǒǻ
.ŽǺò ȯźŸŢ ǰǪǺ ÜǻǺŀş TS (ȯ/ȟ710~) ȯźφǺǯǺɋǻ

0.1 ȢǺȒǺş ǻǺĔǺ ÜǦŐĔęǻ 1 ǥǼŋ ȯźŸɉǻ ɁŸȢǺ ÜǒǺţǻ ȸŋ Ōŋ 25 Ž ȟ 2.5 ǡǻØǺ :**Soluble starch** ǡǻşØǒǻ ǺÎǺǒǻ
.ȧøǻÜ ȷźǒ ǰǪǺ ɍ ÜVS (ȯ/ȯźŋ 0.1~) ǻźĔǒǻ ȯźŸŢ ȸŋ Ōŋ

ȒȞǽş VS (ȯ/ȯźŋ 0.1) ǻźĔǒǻ ȯźŸŢ ȸŋ Ōŋ 0.1 ȢǺȒǺ ÜǒǺţǻ ȸŋ Ōŋ 25 Ž ȟ 2.5 ǡǻØǺ :**Sulfites** ǨĔǺŸÊǒǻ
.ȧøǻÜ ȷźǒ ǰǪǺ ÜTS ǺÎǺǒǻ ȯźŸŢ ȸŋ ǧǻÀÛę

ǺĔźǺò ǒǺţǻ ȸŋ Ōŋ 10 Ž ȟ 5.0 ÂĔōÀǪǽ ȯźŸɉǻ ȷźŎǺ :**Clarity and colour of solution** ȯźŸɉǻ ȷźǒş ǒǺÀò
Colour of ŌǻźÊǒǻ ȷźǒ" ȷǻźǺȝ ǨƠ Ȣźòźŋ źȽ Ǻŧō ȷǿǺŐǺ ǺŋǼǺȝ Gn 3 ɃøǺȞţǻ ȯźŸɉǻ ȸȝ ȼφźǒ ǥǼì ǼǺÂǨ ɍş
.(53 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) "liquids

.ȟ/ƞŸŋ 1.0 ȸȝ ǼǺÂǺ ɍ :**Sulfated ash** ǨǺŸÊţǻ ǻǺŋÀǒǻ

Determination of water by ÀÎĔź ȯøǺō ǦŐǺÀÛǽ ǒǺţǻ ƘĔȞǨ" ȷǻźǺȝ ǨƠ Ȣźòźŋ źȽ Ǻŧō ȸĔȞǺŀ :**Water** ǒǺţǻ
ŌȮÎǒǻ ŌDZɉ ǥǻǺţǻ ȸŋ ȟ 1 ǦǻÀę ŌŧȞǪÊǺş .(145 ǦȞǺÔǒǻ Û1 ǼŸŎǻ) A ǦŐǺÀÛǒǻ Û"the Karl Fischer method
ŌŐǺ ɍ Üǧǻø ǼĔŢǻ ɃǻǺǵÜ ŌȮÎǒǻ ŌDZɉ ǥǻǺţǻ ȸŋ ȟ 0.15 ǦǻÀę ŌŧȞǪÊǺ .ȟ/ƞŸŋ 10 ȸȝ ǒǺţǻ ɁźǪŢ ǼǺÂǺ ɍ ÜɄǝǺŋŸǒǻ
.ȟ/ƞŸŋ 95 ȸȝ ǼǺÂǺ ɍş ȟ/ƞŸŋ 70 ȸȝ ǒǺţǻ ɁźǪŢ

[illegible] R [illegible] 50 [illegible] 5.0 [illegible] :**Acidity** [illegible]
TS [illegible] VS [illegible] 0.02) [illegible]
.([illegible]) [illegible] 0.5 [illegible]

[illegible] 25.0 [illegible] 50 [illegible] 0.10 [illegible] :**Assay** [illegible]
[illegible] 20 [illegible] .TS [illegible] 50) [illegible] 10 [illegible] VS [illegible] 0.05)
0.1) [illegible] .TS [illegible] 100~) [illegible] 15 [illegible]
.[illegible] TS [illegible] VS [illegible]
.$C_6H_{12}O_6$ [illegible] 9.008 [illegible] VS [illegible] 0.05) [illegible] 1 [illegible]

[illegible]

Additional requirements for Glucose for parenteral use

.(56 [illegible] 4 [illegible])"*Parenteral preparation* [illegible]"

[illegible] :**Bacterial endotoxins** [illegible]
([illegible] 30 [illegible] 5 [illegible]) ."Test for bacterial endotoxins [illegible]"
.[illegible] RS [illegible] 0.5 [illegible]

ØØØØØ

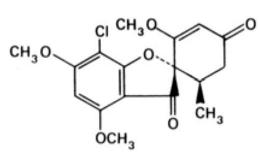
GRISEOFULVINUM

Griseofulvin [illegible]

$C_{17}H_{17}ClO_6$:**Molecular formula** [illegible]

352.8 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

7-Chloro-2′,4,6-trimethoxy-6′*β*-methylspiro[benzofuran-2(3*H*),1′-[2]cyclohexene]-3,4′-dione; (1′*S*-*trans*)-7-chloro-2′,4,6-trimethoxy-6′-methylspiro[benzofuran-2(3*H*),1′-[2]cyclohexene]-3,4′-dione; CAS Reg. No. 126-07-8.

[illegible] **Description** [illegible]

[illegible] **Solubility** [illegible] (~750) [illegible] TS [illegible]

[illegible] R [illegible] R [illegible].

[illegible] **Category** [illegible] Antifungal.

[illegible] **Storage** [illegible].

[illegible] **Additional information** [illegible] 5 [illegible]

[illegible] 30 [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] %97.0 [illegible]

%102.0 [illegible] $C_{17}H_{17}ClO_6$ [illegible].

[illegible] **Identity tests**:

• [illegible] A [illegible] C [illegible] B [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Thin-layer chromatography [illegible] Kieselguhr R1 [illegible] (84 [illegible] 1 [illegible]) [illegible] R [illegible] 1 [illegible] Xylene R [illegible] 10 [illegible] 1 [illegible] 0.50 [illegible] (A) [illegible] R [illegible] 1 [illegible] 0.50 [illegible] (B) [illegible] RS [illegible] 1 [illegible] (254 [illegible]) [illegible] A [illegible] B.

C: [illegible] 5 [illegible] 1 [illegible] (~1760) TS [illegible] 5 [illegible] R [illegible].

D: [illegible] 220 °[illegible].

[illegible] **Specific optical rotation** [illegible] 10 [illegible]

. $[a]_{D}^{20°C}$ = +354 to + 364° ÜR ÆËŋǺŋǿʐʐ

ÛTS àʐöʐǣè ŌĔǮǸ ɄÊõşǿÆĔĿ óʐŸʈ ȡŋ ğäÂÛę 10 ȜŊ ŊŸŋ 10 ȷşǺĿ Ž ȡĦÛł :**Particle size** ǇĔÊŀƨä ǇDzǵ ƂǕ ĘǢĦʈä ȡŋ gÂÛę ŌǬǺł .ʔÀǹǕ gÀŋ ȡĦÛłş TS àʐöʐǣè ŌĔǮǸ ɄÊõşǿÆĔĿ óʐŸʈ ȡŋ ʔÀǹǕ Ōŋ 3.50 ȣǺȒł ǺǮǺŋ Ğǵǻ Ōõ ȄĔŌǨ ǴǺŰǿ ğǺǵǺè 10 ÒĦǺǩ ǺǮęʐʐ ɄDZǺDZà ŏǺÛɖ ȜȓʐǺ ÛǇŸŋ 0.10 Ęȶȝ ğäǽ ǴǴèǺǺŋ ǽȝ gǨDzǵ ǴǸ Ž ǺǬŋşÀÒŋ 5 ȡŋ ȜõǕ gǿʐŸǽ 30 ȡŋ Àǯõǔ ʔÀł ɍ ÜgÀŋ 600 ȻǿÆę ǨǴÒǨ ÿäÆǺǬèǺǽ ÛÀǮÕä ǨƠ 2 ǇŸŋ 0.04 .ǴǺŰǿ Ğǵǻè

Ōŋ 10 Ž ȟ 0.75 ÂĔõÀǬǽ óʐŸʈ ȷʐÓǺ :**Solution in dimethyl formamide** ÆËŋǺŋǿʐʐ ŌĔǮĔŋ ɄəǺǬ Ž óʐŸɫä ȣʐòʐŋ ʐĿ Ǻȶõ ȷǿǺŌł ǺŋÆǺȝ Yw2 ɃǿǺĔĦʈä ȷʐŸöä óʐŸʈ ȡȝ ȼʐö gÆì ÆǺÂǨ ɍş ǢʐǺò R ÆËŋǺŋǿʐʐ ŌĔǮǸ ɄəǺǬ ȡŋ .(53 ǴĦǺÔöä Û1ÆŸÕä) "Colour of liquids ŌəäʐÊöä ȷʐö" ȷäʐǺȝ ǨƠ

ÙǺǺöä ȡŋ Ōŋ 40 Ȝŋ ȟ 1.0 ÀǕǬł :**Matter soluble in light petroleum** ȤĔǺʅä ÙǺǺöä Ž ǴǽäşǾöä gǻǺʈä 10 ǿäÆÕŋ ğäÀŋ 3 ǴŸDZʐΣä ŌÊȣǨ .ǴǹìÀǺş ǻǺǺł ÛĘəǺęǻ 10 gÆŋ ɄȝʐDZÀöä ȷǺÀƨǺǽ ŌȶǨǺ ȤǯÒŋ ÿäÆǺǬèǺǽ R ȤĔǺʅä 1 gÆŋ °ÿ 105 gǿäÀǵ ǴDZǿÆǽ ȤǺDZǩş ɄəǺŋ ÿǺƥ ʔŸȝ ğǺǵǺìÀöä ʈʐȶf ÀǺǻǺ ÛǴìÀǺ ÛR ȤĔǺʅä ÙǺǺöä ȡŋ Ōŋ .ŊŸŋ 2.0 ȡȝ ǴǽǺȶǯöä ȷàş ÆǺÂǺ ɍ ÜǦȝǺè

.ȟ/ŊŸŋ 2.0 ȡȝ ÆǺÂǺ ɍ :**Sulfated ash** ǨǺŸÊʈä ǻǺŋÀöä

10 ȡŋ Àǯõǔ ÆŌǺǺ ɍ Ü°ÿ 105 gǿäÀǵ ǴDZǿÆǽ ǨǽǺǯöä ȷàʐöä ʔǿǬǵ ȤǺDZł :**Loss on drying** ȤĔǺDZʐǬǺǽ ÆŌǺöä .ȟ/ŊŸŋ

ÆĔÊõşǿÆĔĿ óʐŸĦŋ ÀǺǺĦş TS óÆĦǬÊʈä óʐǬǺǯǺɋä ȡŋ Ōŋ 10 ȡŋ Ōŋ 20 Ž ȟ 0.25 āäǾł :**Acidity** Ǵȓʐȶ Σä ÆǢÛǬǺ ɍ ÜÀĦÎȶõ TS óʐǬǺǯǸ/ǨǺöǺǯʐ óʐÆǺöä óʐŸʈ ÿÆǺǬÊǺş VS (ó/óʐŋ 0.02) ğǺǬʐǽÀÒöä ȡŋ ƃǺʅä ÿʐǺǻʐÔöä .(ɄŸǺǬǺę) ÀĦÎȶŸö ʔÛèʐöä ǴÛŌǺöä ȷʐö ʔŸȝ óʐÔΣä ŌDZɉ Ōŋ 1.0 ȡŋ Àǯõǔ

ŏǺÛȝɋ R ŏǺʈä ʈşÂǿǺŋ óʐǬǺǯǺɋä ȡŋ ǴĔʐǺõ ǴĔȶõ Ž ÛǴĔùʐǴȒŋ ǴǬşàʐŋ Ûȟ 0.10 ǴǽäǺę āäǾł :**Assay** ǴÊǺǺÕʈä óʐŸɫä äǾĿ îǺǬ ȡĦǺł .R ŏǺʈä ʈşÂǿǺŋ óʐǬǺǯǺɋǺǽ Ōŋ 100 ƂǕ óʐŸɫä äǾĿ ȡŋ Ōŋ 2 ȤǺǻǺş Ōŋ 200 ǿÆŌǽ ǇDzǵ ǴȶĔÕöä ÿäÆǺǬèǺǽ Û$C_{17}H_{17}ClO_6$ ʔʐǬʈ ÆÊĦǺş ÀǬŋʐǬǺǬ 291 ǴǽäǺę ɄȶȚȝǕ ǴDZʐŋ óʐù ÆǺȝ ǇèǺ 1 ǴǬǺǻǯǽ ǴŌǴù Ž . $(E_{1\ cm}^{1\ \%}= 686)$ 68.6 ǴĔòǺȶǬöä

ø ø ø ø ø

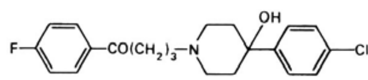
HALOPERIDOLUM

Haloperidol üǸǰǫǐƥǐǴǸǰǁƑǉ

$C_{21}H_{23}ClFNO_2$ ¦**Molecular formula** ǴƐǺǺÂƨǟ Ǵ8ƐÔǿǟ

375.9 ¦**Relative molecular mass** ǴƐǤÊǺǿǟ ǴƐǺǺÂƨǟ ǴŸǪȮǿǟ

¦**Graphic formula** ǴƐǫǺƐǤţǟ Ǵ8ƐÔǿǟ



¦**Chemical name** ȗǝǺƐƭƐȮǿǟ ǈèɍǟ

4-[4-(*p*-Chlorophenyl)-4-hydroxypiperidino]-4′-fluorobutyrophenone; 4-[4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl]-1-(4-fluorophenyl)-1-butanone; CAS Reg. No. 52-86-8.

ƇƐƷ ÜǨȽǺǴǿǟ ǺǺòɉǟ Ƃǚ ǟǿǺř ȒƐǚ ÛǑÒÎǿǟ ƇƐƷ şǚ ȸşǺǑǬ ȸǿǭŸǟ ȧǭȞÊǫ ¦**Description** ǭòǭǿǟ .ǴȞǝǟǺǿǟ

ǟǿǺƊ 20 Žş TS (ȯ/ȟ750~) ȯǭǫǺǯǺɋǟ ȡǫ ǟǿǺƊ 50 Ž ǟǟşǽ ÜǿǺţǟ Ž ǺƐŸƭƷ ǟǟşǽ Ƙȡ ¦**Solubility** ǴƐǫǺǽşǾǿǟ .R Ƙǫɉǟ ȡǫ ǟǿǺƊ 200ş R ÿǿǭǭşǿǭŸȮǿǟ ȡǫ

.Neuroleptic ɉǺȽǾŸǿ ǻǺȒǫ ¦**Category** ǴǺǺǿǟ

.ǿǭȒǿǟ ȡǫ ǴƐƭȚ ÛǺǼƐƊ ǴǾŸ8ǫ ǴǺşǺǵ Ž ȯşǼǺƘǽǭǿǺȚǟ ȘǺǵ Ƶƶ ¦**Storage** ȡǺÂǺǪǿǟ

REQUIREMENTS ƘǴǿǚƱƙǆ!ƒ

%101.0 ȡƷ ǼǺÂǺ ɍş %98.0 ȡƷ ǑǾǺ ɍ Ǻǫ ɁŸƷ ȯşǼǺƘǽǭǿǺȚǟ ȸǭǪƷ ¦**General requirement** ÿǟǺȞǿǟ ƵŸÛǪţǟ .ǴǺǺȮǿǟ ǵǻǺţǟ Ƃǚ ţǭƊǺǿǺǽ ǴǽǭÊȚ Û$C_{21}H_{23}ClFNO_2$ ȡǫ

¦**Identity tests** ȟǐǸǰǇǁƐ ǀ ƐƥƑǴȽǇƐ

• ȡȮǭ ƐǴÛǨ Ǻǫǚ ȒǺǫǼǺǴǪǹɍǟ şǚ Cş A ȡǺǾǺǴǪǹɍǟ Cş B.

ǿǟǺƭƩǟ ǨƠ ǴȞìɉǟ ǴǑÛǺǫ Ž ȗǝǭȒǿǟ ǭƐÛǿǟ ǟǺƐę" ɉǟǭǺƷ ǨƠ ȣǭòǭǫ ǭȽ Ǻƭǒ ÒȞǺǿǟ ɁǺƊƚ :A ǨƠ ǴȞìɉǟ Ž ȋǺÔǪǫɍǟ ǭƐù ȨǽǺÛǪǺ .(43 ǴȞǺÔǿǟ Û1 ǼŸǑǟ) "Spectrophotometry in the infrared region .ȯşǼǺƘǽǭǿǺȚŸǿ *reference spectrum* ȗȞƊǺţǟ ǭƐÛǿǟ Ʒǫ şǚ RS ȯşǼǺƘǽǭǿǺȚǟ ȡǫ ǰǪǺǺ ȸǾǿǟ ǭƐÛǿǟ Ʒǫ ǿǟǺƭƩǟ Òƥ ȯǭŸȚ ȡǫ ǺƭƊǵ 1 ȡǫ ǰǺÂǫ Ž Ǒǫ/ÿǟǺȡşǺǑǫ 15 ǺƐǒǺǪǽ ȯǭȞƭǒ ȋǺÔǪǫɍǟ ǭƐù ȸǼǴƚ :B

[illegible] 350 [illegible] 230 [illegible] 99 [illegible] VS (1 [illegible]) [illegible] 0.49 [illegible] 1 [illegible] 245 [illegible] .([illegible] 1 [illegible] 2 [illegible]) 0.53 [illegible]

[illegible] 1 [illegible]) "Oxygen flask method [illegible]" [illegible] :C [illegible] 80~) [illegible] 3 [illegible] 20 [illegible] (132 [illegible] 10 [illegible] 2 [illegible] TS [illegible]:

Sodium (1 [illegible]) [illegible] 0.1 [illegible] 0.1 [illegible] :(*a*) [illegible] TS [illegible] 0.1 [illegible] alizarinsulfonate TS [illegible].

A [illegible] 2 [illegible] TS (100~ [illegible]) [illegible] 5 [illegible] :(*b*) [illegible] "General identification tests [illegible]" [illegible] .(121 [illegible] 1 [illegible])

Melting range [illegible]: 147 - 152 °[illegible].

Sulfated ash [illegible]: [illegible] 1.0 [illegible].

Loss on drying [illegible]: [illegible] 60 °[illegible] [illegible] 0.6 [illegible] 5 [illegible] 5.0 [illegible].

Related substances [illegible]: [illegible] "Thin-layer chromatography [illegible]" (84 [illegible] 1 [illegible]) [illegible] RS [illegible] 80 [illegible] R 10 [illegible] R 10 [illegible] R [illegible] 10 [illegible] 3 [illegible] :(A) [illegible] 0.050 [illegible] 1 [illegible] :(B) [illegible] 10 [illegible] 1 [illegible] :(C) [illegible] 0.10 [illegible] 1 [illegible] TS2 [illegible] B [illegible] A [illegible] C [illegible].

Assay [illegible]: [illegible] 0.35 [illegible] 30 [illegible] R1 [illegible]

VS (0.1 ...) ... 1 ... (142 ... 1 ...) A ... "Non-aqueous titration" ...
$C_{21}H_{23}$ ClFNO$_2$ ... 37.59 ... VS (0.1 ...)

Additional requirements for Haloperidol for parenteral use

(56 ... 4 ...) "*Parenteral preparations*" ...

... **Bacterial endotoxins** ... (30 ... 5 ...) "Test for bacterial endotoxins" ...
... 71.4 ... RS ... 1 ...

ØØØØØ

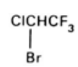
HALOTHANUM

Halothane

Molecular formula: $C_2HBrClF_3$

Relative molecular mass: 197.4

Graphic formula:



Chemical name:

2-Bromo-2-chloro-1,1,1-trifluoroethane; CAS Reg. No. 151-67-7.

Description: ...

Miscibility: ... 400 ... (~750 ...) TS ... R ... R ...

Category: General anaesthetic.

Storage: ... 25 °C.

Additional information: ...

[illegible] 0.12 [illegible] 0.08

Identity tests [illegible]

[illegible] 1 [illegible] 0.1 *tert.*-butanol R [illegible] 2 [illegible]
60~) [illegible] 2 TS [illegible] 260~) [illegible] 0.5 TS [illegible]
[illegible] .2 [illegible] .1 [illegible] TS [illegible]
.R [illegible] 0.3 [illegible] 15 [illegible] °[illegible] 50 [illegible]
[illegible] 0.5 [illegible] 2 1 [illegible] 1 [illegible] :A
[illegible] TS [illegible] sodium alizarinsulfonate TS [illegible] 1) [illegible]
.1 [illegible] 2 [illegible]

[illegible] 1.02 [illegible] 1 [illegible] 2 1 [illegible] 1 [illegible] :B
[illegible] 100 [illegible] VS [illegible] 0.1) [illegible] 30 [illegible] R [illegible]
[illegible] TS [illegible] 1 :(*a*) [illegible] .(5.2 [illegible])
tosylchloramide sodium TS [illegible] 15) [illegible] 0.1 :(*b*) [illegible]
.1 [illegible] 2 [illegible]

TS [illegible] 570~) [illegible] 0.5 [illegible] 2 1 [illegible] 2 [illegible] :C
[illegible] .TS [illegible] 50) [illegible] 0.2 R [illegible] 0.5
[illegible] 0.5 [illegible] 2 [illegible] °[illegible] 50 [illegible]
[illegible] 2 [illegible] TS [illegible] 40) [illegible] 0.1 [illegible] TS [illegible] 1000~)
[illegible] 1 [illegible]

.ρ_{20} = 1.865-1.875 g/ml :**Mass density** [illegible]

3 [illegible] R [illegible] 20 [illegible] 10 [illegible] :**Free halides** [illegible]
TS [illegible] 1000~) [illegible] 1 [illegible] 5 [illegible] 5 [illegible]
[illegible] TS [illegible] 40~) [illegible] 0.2
.([illegible]

[illegible] 10 [illegible] :**Free halogens** [illegible]
.[illegible] TS [illegible] 1

ןזǣÀÒöä ǼĿÊõǚ ȢǝÀĀǭ ȸȠ ƃÀʅä öÀʈä ȸȠ Ōȡ 20 ʒȠ Ōȡ 20 ȐÀĿ :**Acidity or alkalinity** ǦÀźŸÖöä şǚ ǦȑźȶΣä ÀǯõǚÆĿÛǬÀ ɍ ÜTS òźǼÀǯǚ/òşÀÀÕ źȡşƎöä ǦǼźǲøǚ òźŸȚ ȸȠ ǧäÀÛȩ ȐȞǣ ǦĿǝÀʈä ǦÕǤÛöä ƃǚ ȣÀȒĿ .ĘǝÀȩǻ 3 ǥǼȠ ȭÀøźŸõşøǼĿTä Ȓþ òźŸȚ ȸȠ Ōȡ 0.6 şǚ VS (ò/òźȡ 0.01) ÿźÀǻźÔöä ǼĿÊõşøǼĿ òźŸȚ ȸȠ Ōȡ 0.1 ȸȠ .(ɃǻÀȡø) ÀĤÎȶŸö ʔÛèźöä ǦÛÕÀöä ןźö ʔŸʒ òźÔΣä ŌǲɉVS (ò/òźȡ 0.01)

ȸȠ Ōȡ 0.5 ƃşǧä Ž ʒȑźÀş ǥǻäǼè ǧäǣ ÀȚÀȡ Ōõ Ōȡ 25 ǇǲШ ǦźÀǲ ǧÀǼäźÛèä 3 ÿǼÁǬÊĿ :**Thymol** òźȶǯöä ƃǚ ȣÀȒĿ .TS3 òźȶǯöä òźŸȚ ȸȠ Ōȡ 0.5 Ǧǯöǯöä Žş TS2 òźȶǯöä òźŸȚ ȸȠ Ōȡ 0.5 ǦǼÀǯöä Žş ÛøÀǬȠɍä ŌǝÀè ÀÒöä ǼÀøźŸõ Ȣʒǣø ȸȠ Ōȡ 5 ǧÀǼäźÛèä ǫŸǯöä ȸȠ Ōõ

ǦǼÀǭ 30 ǥǼȡ ǥźŌǣ ǧÀǼäźÛèɉä ȐÀĿ .TS ȭÀøźÀŸÊöä Ȓþ/ÿźǼÀǬǼǬöä ǼĿÊõǚ ȢǝÀǭ òźŸȚ ȸȠ Ōȡ 5.0ş R ןźǣ ǦǼäźÛèɍä Ž ǦĿŸÀÊöä ǦÕǤÛŸö ÀÀòɉä ƃǚ āøÀȒöä ȢøÀǤöä ןźŸöä ǥǼì ןźÒǩ .ǧÀŌǤÛöä ŌÔÀǩ ʔøǬǵ øäÀŌǬèŸö õÀǬȿş Ž ƙǬŌźäźǬʈä ƙǬŌǤÛöä Ȣøǭźö ƙǣ ǦÛèźǬȡ Ûô ÀĤǬÊȠ źÜ ʔŸʒ ÀȚĿöǚ ÀǬȚĿ ÀȡǼʒ øÀǬȠɍä ŌǝÀè ʔŸʒ ǦÀźǬɉä .(òźȶǯöä ȸȠ ȟ/ȠŸȡ 0.08-0.08) ƙǬÀȠɉä ƙǬÀǬɍä ƙǬǼäźÛèɍä

Gas äÀȣöä āäÀÎǬèä" ןäźʒ ǨƠ ȣźòźȡ źĿ Àȶõ øÀǬȠɍä ĘǼÛĿ :**Related substances** ǦöÀÎʈä ǻäźʈä TS ןÀǯǚ şøźŸź ȢǬŸǭ şøźŸõ ȢǬŸǭ òźŸȚ (1) ŌǼöÀȚ 3 ÿäǼÁǬèǣ Û(101 ǦȞÀÔöä Û1 ǼŸÕä) "chromatography ȢǬŸǭ şøźŸõ ȢǬŸǭ ȸȠ ÀǬşÀÒȡ 0.05 ʔŸʒ Ƀş ÀΣä øÀǬȠɍä ŌǝÀè (3)ş ÛøÀǬȠɍä ŌǝÀè (2) ÛȢŸȠäǻ øÀĿĤȶǽ ÿǼÁÀş .Ōȡ 1 Ōõ Ž R ןÀǯǚ şøźŸź

¢Àȡ Ƀşɉä Àǭȡ 1.8 øöä ןźÒǩ ÛǇŸȡ 5.0 ȢŸȠäǼöä ȻÀÛǭş Àǭȡ 2.75 ¢òźù ʓÀǲźä ǻźȶʒ öäÀǲźqä ŌǲɉÿǼÁǬÊĿ ȸȠ ȟ 70 ʔŸʒ ǥǼÀǬÊȡ macrogol 400 R òźȡşÀÕÀȡ ȸȠ ȟ 30 ȸȠ ןźÒȟ ÀǬĿȟ ÆȭÀȟ ȸȠ ǦĿźÀõ ǦĿÒǣ ǥźÎȚ ȢǝÀǭ ȸȠ ȟ 30 ȸȠ ןźÒȡ ÀǬĿȡ ÆȭÀȡ ȸȠ ǦĿźÀõ ǦĿÒǣ źÎȚ ȢȩÀǤöş pink firebrick R ȢŸÀǼÀÕöä ɃøäÀΣä ÀǲǼǿä ȘÀǬȞĿş pink firebrick R ȢŸÀǼÀÕöä ɃøäÀΣä ÀǲǼǿä ȸȠ ȟ 70 ʔŸʒ ǥǼÀǬÊȡ dinonyl phthalate R ǧɍÀǯź ŌǼǬźǼ flame ionization ȢøǤŸöä ȸȠǬöä ȣÀÎÒȟş ŌȟÀǥ äÀȣǽ R ƙǲşÀǬÀöä ÿǼÁǬĿş °ÿ 50 ǥøäÀǥ ǦǲøǼǣ ǻźȶȞöÀǣ .detector

Û3 òźŸɉä ȸȠ ǰĸÀöä āäÀÎǬèɍä ÙÛƯ Ž ÛןÀǯǚ şøźŸź ȢǬŸǭ şøźŸõ ȢǬŸǭ ȸȠ ǰǬÀ ȢøǬöä ǥşøØöä ǦǥÀǣ ןźÒǩ Ž allowance ǴȟÀÊǬöä ןźÒÀ Ǽȩ ÜןÀǭźöÀTä ȸȠ ǦΘÀöä ŌŸǩ öÀǯǬèÀǣ ʔÀȠǚ ʔøǼ Ƀɉ ǦĿöÀȠqä ǦǥÀǤöä ȸȠ Ǝõǚ āÀǬǥɍä ȸȡä ÀT Æǝäźì Ƀǚ ŌǲɉÀøşÀȑ ÛןÀǯǚ şøźŸź ȢǬŸǭ şøźŸõ ȢǬŸǭ ȸȠ ǰǬÀ ȢøǬöä ǥşøØöä ǦǥÀǣ āÀÊǥ .2 òźŸɉä ȸȠ ǰĸÀöä āäÀÎǬèɍä ÙÛƯ Ž ÀĿÀş źĿ Àȶõ ¢ÊÀǼ

øøøøø

HYDRARGYRI OXYCYANIDUM

Mercuric oxycyanide ƷƠƏƦǁƐ ǫǏǶǷǏƨ Ǐ ƨ ǀƈ

2ş Hg(CN)₂,HgO ǳŋ ǻǒÂǲ 1 ā ǿÀȬł Ȧŋ ǳŋ ǰÀȦŋ ǳȝ ǥǿȦǤȝ ĘƓəÂöä ǼǰǷȦǼè ɄÊõǁ ׃**Composition** ǼǰõÀǪöä
.CAS Reg. No. 73360-53-9 ÜHg (CN)₂ ǳŋ ǻǒÂǲ

.ǦȞəäÀöä ƇǼȝ ÜǶǤÀȪǩ Ȑǰǖ ş Ȑǰǖ Ƀǿƶǰ ȧƶȞÊŋ ׃**Description** Ƶòƶöä

.TS (ȯ/ȟ 750~) ȯƶǷǯǪä Ž ȷȦşǾöä ȬǯǷę ÜǒǺǰä ǳŋ ǒÂǲ 20 Ž ā ǻşǽ ׃**Solubility** ǦǷǷşǾöä

.(ɄȞȑ ƶţä ȯȦȶȞǪèȲǒ) Antiseptic ÀǷǛǷŋ ׃**Category** ǦÂÀöä

.ǒƶȒöä ǳŋ ǦǰȶƮ ÛǭȦȮǵǖ ǦȬǰ8ŋ ǦǻşȦǵ Ž ĘƓəÂöä ǼǰǷȦǼè ɄÊõǁ ŞȦǵ Ǽƶ ׃**Storage** ǳÂÂǺǪöä

ʔǼõ ÀǱǲȦǺ Ǽęş .ǒƶȒȦǽ ǺǰÛǽ ĘƓəÂöä ǼǰǷȦǼè ɄÊõǁ ȷƶȯ ȯǼǤǪÀ ׃**Additional information** ǦǰƶȦȑǖ ğȦŋƶǰȞŋ
.8ƶÎȮŋ ǼƮ ʔǰȝ ȯƶǰǂä ƙǺÊǩ ǭǼȝ Ǽƶ .ʔÀǹǖ ǻǰƶŋ ȝŋ ǯÀǹä şǖ ǳȞÊöä

REQUIREMENTS ƘǤȞǁƱƙǳ!ƒ

ǳȝ ǼÂÂ ɍş % 14.5 ǳȝ ȬȭÀ Ȧŋ ʔǰȝ ĘƓəÂöä ǼǰǷȦǼè ɄÊõǁ Ƀƶǫȝ ׃**General requirement** ǭȦǰöä ǼǰÛǪţä
.Hg(CN)2 ǳŋ % 85.5 ǳȝ ǼÂÂ ɍş % 82.5 ǳȝ ȬȭÀ ɍ Ȧŋş Û HgO ǳŋ % 17.2

׃**Identity tests** ȟǏǊǇǁƐ ǀƐƥƑǴǪƐ

ǒȦţȦǽ ȬÊ8ł Ûţ ÂǿȦł ÛĘəȦęǻ ȝȒǽ ǥǼŋ Ȭŋ/ȟ 0.05 ÂǰõÀǪǽ ȯƶǰƮ Ž ǦǰèȦɄ ǦȞǰÀò ǳŋ ǥƘ8ò ǦǰÛę ÈȶǷł ׃A
.ȝǜȦè ɄȒƶ ǴÛè ǰǪÀ ÜȧǿƶȯȦǽ ǦȞǰÀÔöä ȭÀÀȴş

ɄÛǰł ȷƶǰöä ÀÀòǖ ȯƶǰƮ ǰǪÀ ÜTS (ȯ/ȟ 80) ǭƶǰèȦƶǤöä ǼÀǻƶÀ ȯƶǰƮ Ȭŋ/ȟ 0.05 ÂǰõÀǪǽ ȯƶǰƮ Ƃǖ 8ȦȒł ׃B
.Àþɉä Ƃǖ ǦǽǿȦȑ ȷƶǰöä ǦǰÀǽ ǦǽȦèƀ TS (ȯ/ȟ 100~) Ȧǰǫƶŋɉä ȯƶǰƮ ǦƶȦȑǖǽ

ǳŋ ǦǰƶȦõ ǦǰȶÕş R àşǼÀǼΣä ğÀÀǰè ǳŋ ȟ 0.05 ǿǼȬŋ Ȭŋ/ȟ 0.05 ÂǰõÀǪǽ ȯƶǰƮ ǳŋ Ȭŋ 1 Ƃǖ 8ȦȒÀ ׃C
ȐȶȞȴş ǰÀţä ʔǰ8À .ǼǰÊõşǿǼǰ ȬȮì ʔǰȝ ǼÀǼΣä ǼǰèÀǪǒ TS (ȯ/ȟ 80~) ǭƶÀǻƶÔöä ǼǰÊõşǿǼǰ ȯƶǰƮ
.ǒȦęǿä ǦǽȦèƀ şǖ ȷƶȯ ǰǪÀ ÜTS (ȯ/ȟ 70~) ȭÀǿƶǰõşǿǼǰTä Ȑþ ȯƶǰȞŋ

ǭƶÀǻƶÔöä ǼǰÊõşǿǼǰ ȯƶǰƮ ǳŋ Ȭŋ 10 8ȦȒÀ ÛǒȦţä ǳŋ Ȭŋ 20 Ž ȟ 1.75 ā ǻǿł ׃**Chlorides** ğäǼÀǿƶǰȮöä
ȬÊ8ł ÛǴǹÀł ÛǻÀǻł .ĘəȦęǻ 10 ǥǼŋ ƵǰÛǒ ƶǓ ʔǰȝ ʔǰ8ȴş TS ǼǰǼǒȦŋǿƶÀöä ȯƶǰƮ ǳŋ Ȭŋ 25ş TS (ȯ/ȟ 80~)
ǦǰƶȦõ Ǧǰȶõ 8ȦȒȴş TS (ȯ/ȟ 130~) ȭÀÀǪǿä Ȑþ ȯƶǰȞŋ ȯǼǼǪÊł ÛğɍÀÊ8Ǯş ǦǵȦìÀöä ȝȶǱł ÛǒȦţȦǽ ǦǽȦèÀöä
ȬǲƗ ɃǼΣä ǿȦǤǪǹɍä" ȷƶÀȝ ǨƠ 8ƶòƶŋ ƶȽ Ȧȶõ ȬȶȞöä ʔÀǲł .Ȭŋ 100 ǿǼȬǽ ǈǲƶǵ ǒÂÛȝǪ ǒȦţä ǳŋ

ȸ Ōŋ 6ş ȯζŸǂǟ ǟØŁ ȸ Ōŋ 40 ÿǟÆÅǫèǟ Û(124 ǦĦÂÔǟ Û1 ÆŸŎǟ) "Limit test for chlorides ğǟÆøζŸÒǟ ÿζǻζÔǟ ÆŀÊõşøÆŀŁ ȯζŸŢ ȸ Ōŋ 10 ǯÂŧł ÿζŧȣǟ ɃøÆĦŋ ƘȒĦǫş .TS (ȯ/ȟ 130~) ŌǟÀǫǟ Ȑ þ ȯζŸŢ

.Ęǝǟęǻ 10 ǥÆŋ ƵŀÛǟ ζÛ ʔŸȝ ǰÂţǟ ʔŸȣłş ClTS ŌøζŸõşøÆŀŢǟ Ȑ þ ȯζŸŢ ȸ Ōŋ 12.25 ȝŋ TS (ȯ/ȟ 80~) TS (ȯ/ȟ 130~) ŌǟÀǫǟ Ȑ þ ȯζŸĦŋ ȯÆĦǫÊǨ Ûğ ɍǟÊȣǟş Ǧǵǟȉǟ ȝŧDzł ÛǑţǟ Ǵȉǟţǟ ŎÊȣł ÛǴȉǟł Û ǻǟł øǟǫȉɍǟ" ȷǟζǟȝ ǨƠ ȣζȍζŋ ζŁ ǟŧõ ŎŧǨǟ ʔÀDzłş .Ōŋ 100 øÆŌǟ ǈDzǵ ǒÛȝq ǒţǟ ȸ ǦŀζǟõǦŀŧõ ȣÂȒłş Ȑ þ ȯζŸŢ ȸ Ōŋ 6ş ȯζŸǂǟ ǟØŁ ȸ Ōŋ 40 ÿǟÆÅǫèǟ Û"Limit test for chlorides ğǟÆøζŸÒǟ ŌDZɉ ɃÆΣǟ .ȟ/ŋŸŋ 0.35 ȸȝ ğǟÆøζŸÒǟ ʔζǫŢ ÆÂ ɍ ÜTS (ȯ/ȟ 130~) ŌǟÀǫǟ

.ÆζÀȍ ǒţǟ ȸ Ōŋ 10 Ž ȟ 0.050 ÂŀõÀǫǟ ȯζŸǂǟ ȷζÒ ؛**Clarity of solution** ȯζŸǂǟ ǒÀȍ

.ȟ/ŋŸŋ 2.5 ȸȝ ÆÂ ɍ Üȷζȉǟǻ ǨƠ (ÆŋÀǫǟ) ȯǨǫȉɍǟ ĘǟÛł ؛**Sulfated ash** ǨǟŸÊţǟ ǻŋÀǟ

10 ȸ ÀǯõÛ ÆŌÂ ɍ Ü°ÿ 105 ǥøǟǵ ǦDZøÆǟ Ǩǟǯǟ ȷàζǟ ʔøǫǵ Ƶǟʑ ؛**Loss on drying** ƵŀÀDzǫǟ ÆŌÀǟ .ȟ/ŋŸŋ

ÛR ȷζǟÒǟ ÆŀÊõÛ ǶǝǟǫȸƂǟǟ ǒţǟ Ž Ōŋ/ȟ 0.05 ÂŀõÀǫǟ ȯζŸŢ ǒŁǟ ŋŸǤøÂ ؛**pH value** ǒŁǟǦǟ ǦŧŀȩPH .8.0-7.46

؛**Assay** ǦÊÂŌţǟ

ȣÂȒł ÛǒţǟȸŌŋ 50 Ž ÛǦŀùζǤȒŋ ǦǫşàζŋÛȟ 0.5 Ǧǟǟę ǟǟØł ؛**For mercuric oxide** ĘǤǝÂǟ ÆŀÊõÛ ŌDZɉ ǦŀǒǟŌǨǟ ȯζŸŢ ÿǟÆÅǫèǟ VS (ȯ/ȯζŋ 0.1) ŌøζŸõşøÆŀŢǟ Ȑ þ ȯζŸĦŋ ÀǟĦłş R ÿζǻζÔǟ ÆøζŸõ ȸ ȟ 1 ȯζŸŢ ȸ Ōŋ 1 Ŏõ .ǦøşÀȓ ğǟĦĦÔǨ ǦÛ ØÅǟłş ǦȍζĦÂţǟ ǥǟţǟ ȷşǻ ǦŀŸŧĦǟ ǻǟǨ .ÀŀÎŧõ TS ȯζǫǟǯÛ/ŌŀǯÆţǟ .(ĘǤǝÂǟ ÆŀǫÆè ǦÊÂŌŋ ŌDZɉ ȯζŸǂǟ ȘǟĦł) .HgO ȸŋŸŋ 10.83 ȕζÒÂ VS (ȯ/ȯζŋ 0.1) ŌøζŸõşøÆŀŢǟ Ȑ þ

ȣÂȒł ÛĘǤǝÂǟ ÆŀÊõÛ ŌDZɉ ǦÊÂŌţǟ ȸ ǰǨǟǟ ȯζŸǂǟ ŎŧǨǫÊł ؛**For mercuric cyanide** ĘǤǝÂǟ ÆŀǫÆè ŌDZɉ ȯζŸŢ ȸ Ōŋ 1 Ŏõ .VS (ȯ/ȯζŋ 0.1) ŌøζŸõşøÆŀŢǟ Ȑ þ ȯζŸĦŋ ǥÀÂĦţǟ ȝǟǫłş R ÿζŀèǨζǤǟ Æǻζ ȸ ȟ 3 .$Hg(CN)_2$ ȸŋŸŋ 12.63 ȕζÒÂ VS (ȯ/ȯζŋ 0.1) ŌøζŸõşøÆŀŢǟ Ȑ þ

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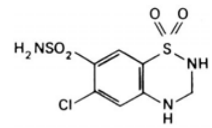
HYDROCHLOROTHIAZIDUM

Hydrochlorothiazide

$C_7H_8ClN_3O_4S_2$ ؛**Molecular formula** ǦŀÂʑǟ ǦȣŀÔǟ

297.7 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

6-Chloro-3,4-dihydro-2*H*-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide; CAS Reg. No. 58-93-5.

:**Description**

:**Solubility** R ... TS (~750 ...) 20 ... 200 ... R.

.Diuretic :**Category**

:**Storage**

REQUIREMENTS

:**General requirement** %98.0 ... %102.0 ... $C_7H_8ClN_3O_4S_2$ ...

:**Identity tests**

:A ... "Spectrophotometry in the infrared region" (... 1 ... 43) ... RS ... *reference spectrum*

:B 10 ... 10 ... R ... disodium chromotropate ... 1 ... 5 ... (~1760 ...) TS ...

:**Heavy metals** ... 1.0 ... "Limit test for heavy metals" 3 ... (1 ... 127) ... A (1 ... 128) ... 10 ...

ɨŋ Ōŋ 10ş ǒǺţǟ ɨŋ Ōŋ 20 Ʒŋ ȟ 0.3 ȒǺǺł ǿǺǪǹɍǟ ȯȥŸŢ ƘȒǶǪ ؛**Free chlorides** ǥǺΣǟ ğǟǼǿȥŸȮǟ
ǨƠ ȣȥȍȥŋ ȥŁ ǺȶȭǴǵǺĭǺǟ Ʒŋ ŌȶȞǟ ʔǺǱł .ǴǺǺŀş ĘǝǺęǻ 5 ǥǼŋ TS (ȯ/ȟ 130~) ȬǺǺǪǺǟ Ȓ þ ȯȥŸŢ
ʔȥǪŢ ǼǺǺ ɍ Ü(124 ǴǶǺȎǟ Û1 ǼŸǑǟ) "Limit test for chlorides ğǟǼǿȥŸȮǟ ŌǱɉ ɃǼΣǟ ǿǺǪǹɍǟ" ɉǟȥǺȝ
.ȟ/ŋŸŋ 0.8 ɨȝ ğǟǼǿȥŸȮǟ

.ȟ/ŋŸŋ 1.0 ɨȝ ǼǺǺ ɍ ؛**Sulfated ash** ǨǺŸȆţǟ ǻǺŋǺǟ

10 ɨŋ ǺǮȭǕ ǼȭǺǺ ɍ Ü°ÿ 105 ǥǿǟǺǵ ǴǱǿǼǟ ǨǟǺǮǟ ɉǟȥǟ ʔǿǪǵ ȤǺǱł ؛**Loss on drying** ȤǺǺǱȥǪǺǟ ǼȭǺǟ
.ȟ/ŋŸŋ

ǴǪşǟȥŋ Ûȟ 0.10 ǴǟǟǺę ȝȓȥǺ ÛǿǺǪǹɍǟ ȯȥŸŢ ŌǱɉ ؛**Diazotizable substances** ǴǟǺǺǼŸǒ ǴŸǟǺȭǟ ǻǟȥţǟ
ǱǱǵ ƃǕ ȤǺǺǺł .R ȯȥǺǺǮţǟ ɨŋ Ōŋ 10 Ž ǟǟǾǺş ǺǺȶǱǵ ǴǱǿǼŋ Ōŋ 50 ǱǱǵ ğǟǟ ǴŸǱȥǵ Ž ÛǴǺùȥǴȒŋ
.ǯǺȶǺş ǒǺţǺǟ ǴŸǱȥΣǟ

ǴŸǱȥǵ ƃǕ ŌǺǺł ÛR ǼǺŋǺǪȥǺŸȅ ȜǝǺǺǪ ɨǺǺǿǪ-1.3- şǿȥŸȭ-6-ȥǺŋǕ-4 ɨŋ ŋŸŋ 5.0 ɉǟȥǺ ÛȜǶǱǺţǟ ȯȥŸǂǟ ŌǱɉ
ȤǺǺǺł .ǯǺȶǺş ǒǺţǺǟ ǴŸǱȥΣǟ ǱǱǵ ƃǕ ȤǺǺǺł .R ȯȥǺǺǮţǟ ɨŋ Ōŋ 1 Ž ǟǟǾǺş ǺǺȶǱǵ ǴǱǿǼŋ Ōŋ 10 ǱǱǵ ğǟǟ
.(Ōŋ/ÿǟǺɖşǺȮŋ 20) Ōŋ 100 ǿǼȭǟ ǱǱǵ ǒǺÛȝɋ ǒǺţǟ ɨŋ ǴǼȥǺȭ ǴǺȶȮǟ ȯȥŸǂǟ ǟǾŁ ɨŋ Ōŋ 4
ǴǱǿǼŋ Ōŋ 50 ǱǱǵ ǺȶǺǺŋ Ōȭ ƙǪŸȎǺǺŋ ƙǪŸǱȥǵ ƃǕ ȜǶǱǺţǟ ȯȥŸǂǟ ɨŋş ǿǺǪǹɍǟ ȯȥŸŢ ɨŋ Ōŋ 5 ŌǺǺł
Ōȭ ƃǕ ȣǺȒł.ǼŁǺΪȭ ÿǼǺǺǺ ǺǺȶǱǵ ǴǱǿǼŋ Ōŋ 50 ǱǱǵ ğǟǟ ǴǮǺǪ ǴŸǱȥǵ ƃǕ ǒǺţǟ ɨŋ Ōŋ 5 ŌǺǺş ǺǺȶǱǵ
ȬǺǿȥŸȭşǿǼǺǟ Ȓ þ ȯȥŸŢ ɨŋ Ōŋ 5ş ǺǱǟǺù ǺȒǶţǟ TS (ȯ/ȟ 10) ÿȥǺǻȥȎǟ ǨǺǺǪ ȯȥŸŢ ɨŋ Ōŋ 1 ǴŸǱȥǵ
ȭǺǪł ÛTS (ȯ/ȟ 25) ÿȥǺȥŋɉǟ ğǺŋǺǺŸȅ ȯȥŸŢ ɨŋ Ōŋ 2 ȣǺȒǺ .ĘǝǺęǻ 5 ǥǼŋ ǿǟǺȬǪȅŸǒ ȭǺǪş T (ȯ/ȟ 70~)
10) ÿȥǺǻȥȎǟ ǴǝǺǺǪ ğǺşǺǩȥŋşǺȭ ȯȥŸŢ ɨŋ Ōŋ 2 ȣǺȒł Ż ŌǝǺȆŸǒ ǿǺȮǪţǟ ǺǺşǼǪǟ Ʒŋ ĘǝǺęǻ 5 ǥǼŋ ǿǟǺȬǪȅŸǒ
ǴŸǱȥΣǟ ǱǱǵ ƃǕ ǒǺţǺǟ ȤǺǺǺł .TS (ȯ/ȟ 150) ÿȥǺǻȥȎǟ ğǺǪȅǕ ȯȥŸŢ ɨŋ Ōŋ 10ş ǺǱǟǺù ǺȒǂǟ TS (ȯ/ȟ
ɨȝ ǿǺǪǹɍǟ ȯȥŸŢ ȋ ǺǪ ǼǺǺǺ ɍ .ǼŁǺΪǟ ŌǺǺŌŋ ÛǺǪŋȥǪǺǪ 500 ǴǟǟǺę ȜȶŢȝǕ ǴǱȥŋ ȯȥù Ž ȋ ǺȶǪǟ ȃǺǾł .ǯǺȶǺş
.(ȟ/ŋŸŋ 10) ȜǶǱǺţǟ ȯȥŸǂǟ ȋ ǺǪ

ȯȥŸŢ ɨŋ ğǟǺÛę 5 ȣǺȒł R ɨǺǼǺƘǴǟ ɨŋ Ōŋ 50 Ž ÛǴǺùȥǴȒŋ ǴǪşǟȥŋ Ûȟ 0.3 ǴǟǟǺę ǟǟǾł ؛**Assay** ǴȆǺǺȭţǟ
ǴǝǺȶǺǟ ǴÛȭǺǟ ʔǿǪǵ ÛVS (ȯ/ȯȥŋ 0.1) ÿȥǺǻȥȎǟ ǼǺȆȭȥǯǺŋ ȯȥŸǶŋ ǺǺǺȅ ǺǺǺǶş azo violet TS şǟǿǟ ǴǱȥȆǺǺǟ
B ǴȭǺǺÛǟ Û"Non - aqueous titration ȜǝǺŋŸǟ Ǜȅȥǟ Ž ǥǺǺǶţǟ" ɉǟȥǺȝ ǨƠ ȣȥȍȥŋ ȥŁ ǺȶȭǴ ÛǴȭŋǺȣǟ ǒǺęǿǺǟ
ɨŋ 14.89 ùȥǺȮǺ VS (ȯ/ȯȥŋ 0.1) ÿȥǺǻȥȎǟ ǼǺȆȭȥǯǺŋ ȯȥŸŢ ɨŋ Ōŋ 1 Ōȭ .(142 ǴǶǺȎǟ Û1 ǼŸǑǟ)
.$C_7H_8ClN_3O_4S_2$

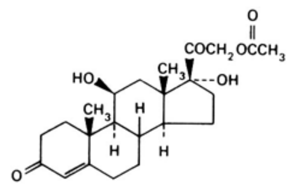
HYDROCORTISONI ACETAS

Hydrocortisone acetate ǊǐǋƦĭƗƥǋǀǋƥǭĭǊǁƐ ǀƑĭƨƈ

$C_{23}H_{32}O_6$ ¦**Molecular formula** ǦƎǺƨƼ ǦȢƎǾǛ

404.5 ¦**Relative molecular mass** ǦƎƠǛƮ ǦƎǺƨƼ ǦǘǛǾǛ

¦**Graphic formula** ǦƎǺƎǛƫ ǦȢƎǾǛ



¦**Chemical name** ȣǝƎƪƏǾǛ ǋèƥ

21-(Acetyloxy)-11β,17-dihydroxypregn-4-ene-3,20-dione; 11β,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate; CAS Reg. No. 50-03-3.

.Cortisol acetate ǾşƏƎǿƺǾǛ ǧƏǫƎèǛ ¦**Other name** ȀǹǿǛ ǋèƥ

.ǦǀǝǛȀǾǛ ǨƎƷ ǛǦƏǀǾǛ ȐƎǛ şǛ ȐƎǛ ƁǿƺǛ ȧƺǀƎƞ ¦**Description** ƺǒƺǾǛ

ǛƦ ȳǿƺƺşǿƺǛǾǛş TS (ǿ/ȟ 750~) ǿƺǛƎǛǭǛ Ž ǰǛşǾǛ ǴƎǀǛ Ǜ ǿǛƫǛ Ž ƎǛƪƷ ǟǛşǛ Ƙǫ ¦**Solubility** ǦƎǛǛşǾǛ

.R ƘǫǰǛ Ž ƎƎǊ ǰǛşǾǛ ǴƎǀǛ

.Adrenocortical steroid ƁȀƮǔ ȀǛƏê ǛşƘǫè ¦**Category** ǦǛǛǾǛ

.ǿƺȒǾǛ ǭƞ ǦƎƪƮ ǛǛƎǊ ǦǛǛǛƞ ǦǛşǛǧ Ž ǰşƏƎǿƺǾşǿƎƎǛ ǧƏǫƎèǛ ȘǛǧ Ǝƶ: **Storage** ǭǛƎǛǛǾǛ

ƷƞȂ ǛƗ 220 ǦǛǛǛ ǥǿǛǛǧ ǦǊǿƎǛ ǰşƏƎǿƺǾşǿƎƎǛ ǧƏǫƎèǛ ȀƸǛǛ ¦**Additional information** ǦƎƺǛƥǛ ǧǛƞƺǛƞ .ǛǾǛǾǛ

ƎǛǛǛ ƥş %97.0 ǭƷ ǛǛǛ ƥ ǛƞƷǛƷ ǰşƏƎǿƺǾşǿƎƎǛ ǧƏǫƎèǛ ƁƺǫƠ ¦**General requirement** ȳǛǛǾǛ ǼǛǛǫƫǛ .ǦǛǛǾǛ ǥǛǛƫǛ ƂǛ ƫƺǊǛǛǛ ǦǛƺƮƮ ǛƐ$C_{23}H_{32}O_6$ ǭƞ %102.0 ǭƷ

¦**Identity tests** ǀĭǋǋǊǁƐ ǀƐƥƑǴƢƐ

.B ǿǛǛǛǹƥǛ şǛ A ǿǛǛǛǹƥǛ ǛƞǛ ǜƎǛǛ ǭǾƹ •

ǿǛǛƪƩǛ ƘƠ ǦǛǛǰǛ ǦǛǛǛǛƞ Ž ȣǝƺȒǾǛ ƺƎǛǾǛ ǟǛƎǧ" ǰǛƺǛƷ ƘƠ ǛƺǒƺƞƺȽ Ǜƪǔ ǾǛǛǛǾǛ ƁȀǊƺ :A ƘƠ ǦǛǛǰǛ Ž ǛǛǾǫƞƥǛ ƺƎǛ ǜǛǛǛǛǛ .(43 ǦǛǛǾǛ Ǜ1 ǛǛǾǛ) "Spectrophotometry in the infrared region

reference spectrum ȖȟDZǍţǟ ǖǇÛöä Ʒŋ şǚ RS ɉşÂǨǿǕõşǿǼȚǟ ğǍǪèǚ ȸŋ ǰǪǍ ɃØöä ǖǇÛöä Ʒŋ ŏäǍŧΣǟ .ɉşÂǨǿǕõşǿǼȚǟ ğǍǪèɉ

"Thin-layer chromatography ČŐǋȩǍöä ČŐǤÛöä āäǍÎǪèǟ" ɉǟǕǍʒ ǨƠ ȣǕòǕŋ ǕȽ Ǎŧõ ǿǍǤǪǹɍǟ ĘǘÛɫ :B R ǼȵŋǍŋǿǕǍöä ȸŋ ÿǕDzǵ 10 ȸŋ ǰǍÂŋş ČŸǰ8ŋ ǥáǍŧõ Kieselguhr R1 ǥáǍŋ ÿäǼǺǪèǍǣ Û(84 ČĦǍÔöä Û1 ǼŸŎä) ǼǍØţǟ ȯǕòş ǼȞǣş .ŌǟǍÊöä ǴÛè ǨƠ ǈŸŋ 5 ǦǟǍȩ ǍȾÊŧ8ǣ ÛČĦǍÔöä ǼǍǍÎǪǒ R ɉǕǪèɉǟ ȸŋ ǍŧDzǵ 90ş ʔØǪǵ ǦǕǍ8öä ǥǿǟǍǵ ČDZǿǼǣ ǿǟǍÔǪèŶǒ ōǍǪǩş āäǍÎǪèɍǟ ǥƘDzǵ ȸŋ ČĦǍÔöä ţÂØǍɫ ÛŌȩɉǟ ʔŸʒ ǈè 16 ţǍǍǨǿɍ ŌŧȞǪÊǩş .ȼÊǍǹ āäǍìqǟ ǞǍΘǟ Ž āäǍÎǪèɍǟ ĘǘÛǩş Ǧʒǟè 2 ȯŸǹ ǦǟǍÎţǟ ČĦǍÔöä ŌŧȞǪÊǩş .ǍŋǍǪ ǼǍØţǟ ǍǺǤǪǍ 2 ČĦǍÔöä ʔŸʒ ǂÔǍǍŋ ĘǘÛɫ .R ÿǿǕǕşǿǕŸǑöä ȸŋ ǍŧDzǵ 25ş R ȸǍǕǿǕǪöä ȸŋ ǍŧDzǵ 75 ȸŋ ǰǍÂŋ ōǍĦǪŋ ǿǕÛǷ ɃǕƷ :(A) ȯǕŸɨǟ ÛR ȯǕǒǍǯǼţǟ ȸŋ ǍŧDzǵ 1ş R ÿǿǕǕşǿǕŸǑöä ȸŋ ÿǕDzǵ 9 ȸŋ ǰǍÂŋ Ž ƙǍǭǟ ƙȯǕŸȚ ȸŋ ǍǪǒşǍǑŋ 1 Ōõ Ž RS ɉşÂǨǿǕõşǿǼȚǟ ğǍǪèǚ ȸŋ ŊŸŋ 2.5 ɃǕƷ :(B) ȯǕŸɨǟş Ōŋ 1 Ōõ Ž ǿǍǤǪǹɍǟ ǥáǍŋ ȸŋ ŊŸŋ 2.5 ǥƘDzǵ ȸŋ ČĦǍÔöä ţÂØǹ ǼȞǣş .ǈè 15 ţǍǍǨǿǟ ʔŸʒ ōǍĦǪţǟ ǿǕÛöä ǴǤÔǍ ʔØǪǵ ČĦǍÔöä ōǍǪǩ .Ōŋ ȯǕŸĦŋ ǽǍǍɫ ÛČŐǋȩǻ 15 ǥǼŋ °ÿ 120 ǥǿǟǍǵ ČDZǿǼǣ ȸǺÊɫ ÛğǍǤǍØţǟ ǍǺǤǪǩ ʔØǪǵ ŏǟǕȚǟ Ž ǖDzǪǒ ōǍǪɫ ÛāäǍ ÎǪèqǟ ÙÛƯ ÒĦǍǩş ǻǶǪǒ ōǍǪɫ .ĘǝǍȩǻ 10 ǥǼŋ °ÿ 120 ǥǿǟǍǵ ČDZǿǼǣ ȸǺÊɫ Ż ȸŋş TS ȯǕǒǍǯǍǚ/ŌǍǿǕǍŸÊöä Ȑƥ ȯǕŸɨǟ ȸŋ ǰǪǍǨ ȖØǪöä ČǼÊǼǝǍöä ČȞŐǤöä ĘǕǟǕǩ .(ǍǪŋǕǒǍǹ 365) ČǼDzÊǍǍǤöä ȧǕǕ ČĦìɉǟ Žş ǿǍȾǍöä ŏǕȑ Ž āäǍÎǪèɍǟ .B ȯǕŸɨǟ ȸŋ ČΘǍǍöä ŌŸǩ Ʒŋ ǥǼÎöäş ǍȾȚţǟş ƷȩǟǕţǟ Ž A

ÛR ɉǍÊõǕǍǼöä Ž Ōŋ/ŊŸŋ 10 ÂǼōǍØǪǣ ȯǕŸȚ ŌŧȞǪÊǍ :**Specific optical rotation** ȖʒǕǍöä ɃǍÔǤöä ǍǍşǼǪöä .$[a]_{D}^{20°C} = +157 \text{ to } +168°$

10 ȸŋ ǍǯõǚǼŌǍǍ ɍ Û°ÿ 105 ǥǿǟǍǵ ČDZǿǼǣ ǨǟǍǯöä ɉàǕöä ʔØǪǵ ǖǍDzɫ :**Loss on drying** ǖǇǍDzǪǒǍǣ ǼŌǍöä .ȟ/ŊŸŋ

ČŐǋȩǍöä ČŐǤÛöä āäǍÎǪèǟ" ɉǟǕǍʒ ǨƠ ȣǕòǕŋ ǕȽ Ǎŧõ ǿǍǤǪǹɍǟ ĘǘÛɫ :**Related substances** ČŏǍÎţǟ ǻǟǕţǟ şǿǕŸõ ȖǝǍǪ ȸŋ ǍŧDzǵ 95 ȸŋ ǰǍÂŋş ČŸǰ8ŋ ǥáǍŧõ R2 ǍǑǼŸǼÊöä ČŋŶȽ ÿäǼǺǪèǍǣ "Thin-layer chromatography ȸŋ ǍǪǒşǍǑŋ 1 ČĦǍÔöä ʔŸʒ ǂÔǍǍŋ ĘǘÛɫ .ōǍĦǪŋ ǿǕÛõ ŏǍţǟ ȸŋ ǍŧDzǵ 0.2ş R ȯǕǒǍǯǼţǟ ȸŋ ÿǕDzǵ 5ş R ɉǍǯǍǚ ȸŋ ŊŸŋ 15 ɃǕƷ :(A) ȯǕŸɨǟ ÛR ȯǕǒǍǯǼţǟ ȸŋ ǍŧDzǵ 1ş R ÿǿǕǕşǿǕŸǑöä ȸŋ ÿǕDzǵ 9 ȸŋ ǰǍÂŋ Ž ƙǍǭǟ ƙȯǕŸȚ ȸŋ ČĦǍÔöä ţÂØǹ ǼȞǣş .Ōŋ 1 Ōõ Ž ǿǍǤǪǹɍǟ ǥáǍŋ ȸŋ ŊŸŋ 0.30 ɃǕƷ :(B) ȯǕŸɨǟş Ōŋ 1 Ōõ Ž ǿǍǤǪǹɍǟ ǥáǍŋ ÛĘǝǍȩǻ 10 ǥǼŋ °ÿ 105 ǥǿǟǍǵ ČDZǿǼǣ ȸǺÊɫ Ż ÛğǍǤǍØţǟ ǍǺǤǪǩ ʔØǪǵ ŏǟǕȚǟ Ž ǖDzǪǒ ōǍǪɫ ÛāäǍ ÎǪèɍǟ ǥƘDzǵ ȯǕŸɨǟ ȸŋ ǰǪǍǨ ČȞŐǣ ǦǍǚ ɉǕǑǩ ɍ .(ǍǪŋǕǒǍǹ 254) ČǼDzÊǍǍǤöä ȧǕǕ ČĦìɉǟ Ž āäǍÎǪèɍǟ ÙÛƯ ÒĦǍǍş ǻƎǪǒ ōǍǪǩ .B ȯǕŸɨǟ ȸŋ ČΘǍǍöä ŌŸǩ ȸŋ ǥǼì ǍǯõǚǼ ÛČǼÊǼǝǍöä ČȞŐǤöä ŏǍǍǯǪèǍǣ Û(A)

ǒǻÛʒq TS (ȯ/ȟ750~) ȯɀǻǯǻq ȸɳ ǦɀǼõ ǦȽȶõ Ž ÛǦȽüɀǦȒɳ Ǧφşäɀɳ Û ŊŸɳ 20 Ǧää ā āǾł ¦**Assay** ǦÊǺÕʈā

ȸɳ ɭè 1 ǦφǺǯǽ ǦÕǦù î ǺΊ ā ǺÕł .¢ÊǺφ ǼǾʈǽ Ōɳ 100 БǕ ȯɀŸǂā ǾȽ ȸɳ Ōɳ 5.0 ɀǺǺł ÜŌɳ 100 øǼÕǽ ɭDzǵ

ʒɳ ǦφøǺÕʈǽ ǥǺǻǺʈā ǥǻʈā Ž $C_{23}H_{32}O_6$ øāǼÕɳ ǼÊȞł .ǺŊɀφǺφ 242 Ǧää Ʉȶ ʒǕ ǦDZɀɳ ȯɀù Ž ɀǺǺʈā ȯɀŸǂā

ɀȽÛöā āǺȽÕɳ Ž ɄȞDZǺʈā ȯɀŸǂā î ǺΊ ȷɀȮǺ ȷǕ Ǽƶ .ȸɧǺΏöāş ¢āǺÎǽ î ɀȞǺʈā RS ȷşǺȽǩøɀõşøǼȽTā ǧǺȽèǕ

1 ǦφǺǯǽ ǦÕǦÛö î ǺȶΏöā ǼÊȞłş āǺȽÕŸö ɭè 2 ÈȽÕǩ ǧāKDzǵ ȳāǼǺΏèā ŌȒǺǺ) 0.40 ± 0.02 ǦǺǺȮǽ ǺȽǩʈā Ʉəɀ Ȓöā

.(ɭè

ØØØØØ

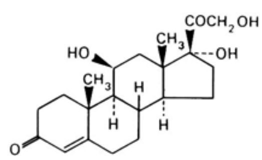
HYDROCORTISONUM

Hydrocortisone DžNjȒĩŀþNjǀNjþǫĩǉ

$C_{21}H_{30}O_5$ ¦**Molecular formula** ǦȽǺÂƨā Ǧ8ȽÔöā

362.5 ¦**Relative molecular mass** ǦȽǦÊǺöā ǦȽǺÂƨā ǦŸΏȮöā

¦**Graphic formula** ǦȽφǺȽǦʈā Ǧ8ȽÔöā



¦**Chemical name** ɄəǺȽȶȽȮöā ɭèɍā

11β,17,21-Trihydroxypregn-4-ene-3,20-dione; CAS Reg. No. 50-23-7.

.Cortisol ȯşǺȽǩøɀõ ¦**Other name** Ǻǹɇā ɭèɍā

.ǦȞəāǺöā ÇǼʒ ÜǺǦǺÕǩ ȒȽǕ şǕ ȒȽǕ Ƀøɀǽ āɀȞÊɳ ¦**Description** ɀòɀöā

TS (ȯ/ȟ750~) ȯɀφǻǯǻq Ž ȷǺşǾöā ŌȽŸɳ ÜR ƘΏǰǻş ǒǻʈā Ž ǺǼDZ ȷǺşǾöā ǴȞǕì ¦**Solubility** ǦȽφǺşǾöā

.R ȳøɀɀşøɀŸȮöā Ž ȷǺşǾöā ǴȽǕì ÜR ȷɀΏȽèǰǻş

.Adrenocortical steroid ȸǺȚõ ǺÎȩ ǼǺşƘΏè ¦**Category** ǦǺǺöā

.ǒɀȒöā ȸɳ ǦȽȶȚ ÛǽǼȽDZ ǦÕŸ8ɳ ǦǺşǻǵ Ž ȷşǺȽǩøɀõşøǼȽTā ȘǺǵ Ǽƶ ¦**Storage** ȸǺÂǺΏöā

ʒɳ °ȳ 214 Ǧää ǥøāǺǵ ǦDZøǼǽ ȷşǺȽǩøɀõşøǼȽTā ǺȚÔǺǺ ¦**Additional information** ǦȽɀǺȑǕ ǧǺɳɀŸȞɳ

.ÕÐǺΏöā

[illegible] %97.0 [illegible] **General requirement** [illegible] $C_{21}H_{30}O_5$ [illegible] %102.0 [illegible]

Identity tests [illegible]

• [illegible] A [illegible] B.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) [illegible] Kieselguhr R1 [illegible] 10 [illegible] R 90 [illegible] 16 [illegible] R [illegible] 5 [illegible] 2 [illegible] 9 [illegible] R 2.5 [illegible] (A): [illegible] 2.5 [illegible] 1 [illegible] (B): [illegible] 1 R [illegible] 15 [illegible] RS [illegible] 1 [illegible] 120 °[illegible] 10 [illegible] 120 °[illegible] TS [illegible] 15 [illegible] 365 [illegible] A [illegible] B.

Specific optical rotation [illegible] 10 [illegible]
$[a]_{D}^{20°C} = +150$ to $+165°$.

Loss on drying [illegible] 105 °[illegible] 10 [illegible]

Related substances [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) [illegible] R2 [illegible] 77 [illegible]

[illegible] 1.2 [illegible] 8 [illegible] 15 [illegible] 1 [illegible] 9 [illegible] 1 [illegible] 0.30 [illegible] :(B) [illegible] 1 [illegible] 15 [illegible] :(A) [illegible] 1 [illegible] 10 [illegible] 105 [illegible] (A) [illegible] (254 [illegible]) [illegible] .B [illegible]

[illegible] TS (~750) [illegible] 20 [illegible] :**Assay** [illegible] 1 [illegible] 100 [illegible] 5.0 [illegible] 100 [illegible] $C_{21}H_{30}O_5$ [illegible] 242 [illegible] RS [illegible] 1 [illegible] 2 [illegible] 0.02 ± 0.44 [illegible]

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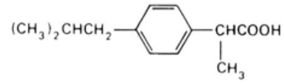
IBUPROFENUM

Ibuprofen [illegible]

$C_{13}H_{18}O_2$:**Molecular formula** [illegible]

206.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

p-Isobutylhydratropic acid; *α*-methyl-4-(2-methylpropyl)benzeneacetic acid; 2-(*p*-isobutylphenyl)propionic acid; CAS Reg. No. 15687-27-1.

[illegible] :**Description** [illegible]

[illegible] 1 [illegible] TS (~750) [illegible] 1.5 [illegible] :**Solubility** [illegible]

[illegible] 1.5 [illegible] 2 [illegible]

[illegible] **Category**: Analgesic [illegible] anti-inflammatory.

[illegible] **Storage**: [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 98.5% [illegible] 100.5% [illegible] $C_{13}H_{18}O_2$ [illegible]

[illegible] **Identity tests**:

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" (43 [illegible] 1) [illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] 0.25 [illegible] (0.1 [illegible]) VS [illegible] 0.25 [illegible] 220 [illegible] 350 [illegible] RS [illegible] (0.1 [illegible]) VS [illegible] 264 [illegible] 273 [illegible] 259 [illegible] 264 [illegible] 273 [illegible] 3% [illegible] 1 [illegible] 264 [illegible] 273 [illegible] 0.46 [illegible] 0.39 [illegible] 2 [illegible] 1 [illegible]

C: [illegible] 76 °[illegible]

[illegible] **Heavy metals**: [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 3 [illegible] 1 [illegible] 127) [illegible] A [illegible] 1 [illegible] 128) [illegible] 10 [illegible]

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible]

[illegible] **Loss on drying**: [illegible] phosphorus pentoxide [illegible] 0.6 [illegible] 5 [illegible] 5.0 [illegible]

Related substances

A: "Gas chromatography"

TS 0.10 (101

diazomethane

A1 A2. R 2

A1 3.0 1.8

silanized kieselguhr R3 9 20 M R 1

flame ionization detector R 135 °.

2.5

0.010 1.0

0.003

A2 3.0 1.8

R 0.2 methyl silicone gum R 0.5

silanized kieselguhr R4 9.3 cyanoethylmethyl silicone gum

flame ionization detector R 170 °.

6.0 1.5

0.010 1.0

A1 A2 0.015

B: "Thin-layer chromatography"

R 1-15 R1 (84

R 1 R 5

1 100 :(A) R 5

1 1 :(B)

R 10

20 120 ° (TS 100~)

A (365)

B

[illegible] Assay: [illegible] 0.4 [illegible] 100 [illegible] (~750 g/l) TS [illegible] (0.1 mol/l) [illegible] TS [illegible] TS [illegible] 1 [illegible] (0.1 mol/l) VS [illegible] 20.63 [illegible] VS [illegible]
$C_{13}H_{18}O_2$.

ØØØØØ

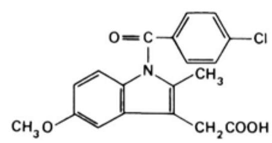
INDOMETACINUM

Indometacin [illegible]

[illegible] **Molecular formula**: $C_{19}H_{16}ClNO_4$

[illegible] **Relative molecular mass**: 357.8

[illegible] **Graphic formula**:



[illegible] **Chemical name**:

1-(*p*-Chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid; 1-(4-chlorobenzoyl)-5-methoxy-2-methyl-1*H*-indole-3-acetic acid; CAS Reg. No. 53-86-1.

[illegible] **Description**: [illegible]

[illegible] **Solubility**: [illegible] (~750 g/l) TS [illegible] R [illegible] R.

[illegible] **Category**: Analgesic [illegible] anti-inflammatory.

[illegible] **Storage**: [illegible]

[illegible] **Additional information**: [illegible] polymorphism. [illegible] RS.

General requirement: %98.0 – %101.5 $C_{19}H_{16}ClNO_4$

Identity tests:

• A, B, C.

A: Spectrophotometry in the infrared region (43) – RS – *reference spectrum*.

B: 0.1 – 100 – 0.5 (0.1) VS – TS (1) – 1 – 1 – 0.5 – (~1760) TS – 5 – 5 – TS (1) – 1 – 1 – 0.5 – (~420) Ts.

C: 160 °.

Heavy metals: 1.0 – Limit test for heavy metals 3 (127) – A (128) – 20 –/–.

Sulfated ash: 2.0 –/–.

Loss on drying: 105 ° – 0.6 – 5 – 5.0 –/–.

Related substances: Thin-layer chromatography (84) – R2 – TS (45) – 7 – 10 – R – 3 R – (A): 20 – 1 – (B): 0.10 – 1.

[illegible] (254 [illegible]) [illegible]

Assay: [illegible] 0.33 [illegible] 75 [illegible] 15 [illegible] R [illegible] TS [illegible] VS (0.1 [illegible]) [illegible] potentiometrically [illegible] 1 [illegible] VS (0.1 [illegible]) [illegible] 35.78 [illegible] $C_{19}H_{16}ClNO_4$.

ØØØØØ

IODUM

Iodine [illegible]

Molecular formula: I_2

Relative molecular mass: 253.8

Chemical name: Iodine; CAS Reg. No. 7553-56-2.

Description: [illegible]

Solubility: [illegible] (~750) [illegible] TS [illegible] R [illegible] R [illegible] R [illegible] R.

Category: External antiseptic.

Storage: [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 99.5% [illegible] 100.5% [illegible] I_2.

:**Identity tests**

0.05 ... (ò/ȟ750) ... 10 ... 0.05 ... :A

... 10 ...

... TS ... :B

...

... 10 ... 1.5 ... :**Chlorides and bromides** ...

... .R ... 0.5 ... 15 ...

... 5 ... 20 ...

... 3ş TS (ò/ȟ260~) ... 1.5 (...)

... 1.5 ... 10 ... (ò/ȟ 40) ...

... 1 ... TS (ò/ȟ1000~) ...

... 0.25ş ... 10.75 ...

... 0.3ş TS (ò/ȟ130~) ... 0.2ş VS (ò/òzη 0.01)

.ȟ/ŋŸη 0.25 ... (ò/ȟ40~)

... 5 ... :**Cyanides** ...

... 1ş TS (ò/ȟ15) ... 0.2 ...

... TS (ò/ȟ70~) ... TS (ò/ȟ80~)

...

... 1 ... :**Non-volatile residue** ...

.ȟ/ŋŸη 1.0 ... 105 ... 1 ...

... 1 ... 0.5 ... :**Assay** ...

... 1 ... 50 ... 5 ... R ...

1 ... TS ... VS (ò/òzη 0.1) ... TS (ò/ȟ70~)

.I ... 12.69 ... VS (ò/òzη 0.1) ...

...

Additional requirement for Iodine for parenteral use

.(56 ... 4 ...) "*parenteral preparation* ...

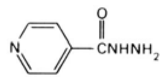
ISONIAZIDUM

Isoniazid [illegible]

$C_6H_7N_3O$:**Molecular formula** [illegible]

137.1 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

4-Pyridinecarboxylic acid hydrazide; CAS Reg. No. 54-85-3.

.Isonicotinic acid hydrazide [illegible] :**Other name** [illegible]

[illegible] :**Description** [illegible]

[illegible] (~750) [illegible] 40 [illegible] 8 [illegible] :**Solubility** [illegible]
[illegible] R [illegible]

.Tuberculostatic [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

%101.0 [illegible] %98.0 [illegible] :**General requirement** [illegible]
[illegible] $C_6H_7N_3O$ [illegible]

:**Identity tests** [illegible]

• [illegible] A [illegible] B [illegible] C.

A: [illegible]
[illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region
[illegible] RS [illegible] *reference spectrum* [illegible]

B: 0.05 [illegible] 1 [illegible] R [illegible]

[illegible] TS (ό/ȟ10) [illegible] 10 [illegible] 2 [illegible] 0.1 [illegible] :C
[illegible] TS (ό/ȟ 600~) [illegible] 5 [illegible]
[illegible] 227 [illegible] 105 [illegible]

.°ÿ 174-170 :**Melting range** [illegible]

[illegible] 1.0 [illegible] :**Heavy metals** [illegible]
(127 [illegible] 1 [illegible]) 1 [illegible] "Limit test for heavy metals [illegible]"
.ȟ/[illegible] 20 [illegible] (128 [illegible] 1 [illegible]) A [illegible]

[illegible] 10 [illegible] 0.50 [illegible] :**Clarity and colour of solution** [illegible]
[illegible]

.ȟ/[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

10 [illegible] 105 [illegible] :**Loss on drying** [illegible]
.ȟ/[illegible]

[illegible] R [illegible] 0.05 [illegible] :**pH value** [illegible]
.8.0-6.0

[illegible] :**Free hydrazine** [illegible]
98 [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography
[illegible] 10 [illegible] 2 [illegible] R [illegible]
1 [illegible] 0.10 [illegible] :(A) [illegible] 1 [illegible] R [illegible] 1 [illegible]
[illegible] 1 [illegible] 20 [illegible] :(B) [illegible]
[illegible] TS3 [illegible]-4 [illegible]
[illegible] A [illegible] B [illegible]
[illegible]

.[illegible] 100 [illegible] 0.25 [illegible] :**Assay** [illegible]
TS (ό/ȟ 250~) [illegible] 20 [illegible] 100 [illegible] 25.0 [illegible]
[illegible] .TS [illegible] 3 R [illegible] 0.2
[illegible] VS (ό/ό 0.0167)
VS (ό/ό 0.0167) [illegible] 1 [illegible]

.$C_6H_7N_3O$ 3.429

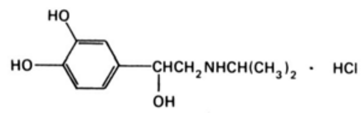
ISOPRENALINI HYDROCHLORIDUM

hydrochloride Isoprenaline

$C_{11}H_{17}NO_3$, HCl :**Molecular formula**

247.7 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

3,4-Dihydroxy-α-[(isopropylamino)methyl]benzyl alcohol hydrochloride; 4-[1-hydroxy-2-[(1-methylethyl)amino]ethyl]-1,2-benzenediol hydrochloride; α-[(isopropylamino)methyl]protocatechuyl alcohol hydrochloride; CAS Reg. No. 51-30-9.

:**Description**

:**Solubility** (750~)

:**Category** .Bronchodilator

:**Storage**

:**Additional information**

REQUIREMENTS

:**General requirement** %97.5 %101.0 $C_{11}H_{17}NO_3$, HCl

:**Identity tests**

350ş ÀǪŋƺǵÀǽ 240 ƙǽ ǯǻƺŋǰǻ ȯǻƺùǕ Ž ǼŁÀÎƗ ÀŋǼÀ3 ÛŌŋ/ŊŸŋ 0.050 ÂŁÕÀǪǽ ȯƺŸǂ î ÀÔǪŋɎǻ ƵŁù ɃǼǤƗ :A

.0.50 ǤǽǻÀę ǻǾŁ ǤDZƺʈǻ ȯƺù Ž ǈè 1 ǤǵÀǺǯǽ ǤŐǤù î ÀǪ ɈƺȮÀ ÜÀǪŋƺǵÀǽ 280 ǤDZƺʈǻ ǤǽǻÀę ǼŁȶŢ3Ǖ ǼȍÀÔǪŋǕ ÛÀǪŋƺǵÀǽ ǤǝǿǻǻǺ ȯƺŸŢ ȡŋ Ōŋ 10 ÀƵǻǼǵǕ ɃƺƠ ÛƙǪŸDZƺǵ ȡŋ ŌÕ ƂǕ Ōŋ/ŊŸŋ 1.0 ÂŁÕÀǪǽ ȯƺŸŢ ȡŋ Ōŋ 1 ȣÀȒƗ :B

ǼȒÀǕ ȡȮƨ ÜTS Û6.4 ǒÀŁÀǽ ǧǻǽ ǧÀÀÊƺ ǤǝǿǻǻǺ ȯƺŸŢ ȡŋ Ōŋ 10 ɁÀǹǰǻ ɃƺƠş ÛTS Û3.4 ǒÀŁÀǽ ǧǻǽ ǧɎÀǯƺ ǵǼŋ ǿǻÀŌǪèȒǒ ŌÀǪǩ ÛVS (ȯ/ȯƺŋ 0.1) ǻƺŁǒǻ ȯƺŸŢ ȡŋ Ōŋ 0.5 ȣÀȒƗ .¢ÊÀǵ ǒÀŁÀǤǒǻ ǧǻǽ ɁÀǹǕ ǧÀǝǿǻǻǺ ȯÀȶŇǪèǻ Ƀǽ ȯƺŸǂǻ Ž ǼÀǼì ÀβǕ Ɉƺǒ ǰǪÀÀ .VS (ȯ/ȯƺŋ 0.1) ȳƺÀǻƺÔǒǻ ǧÀÀŸèƺŁǵ ȯƺŸŢ ȡŋ Ōŋ 2 ȣÀȒƗş ȨǝÀęǻ 5

.(levarterenol ȯƺÀÀǨǩǿÀÀŁǒ ȡ3 ǼÀŁǪ) 6.4 ǒÀŁÀǤǒǻ Ƀǽ ȯƺŸǂǻ Ž ǼÀǼì ɄDZÊÀÀǽ - ÀβǕ Ɉƺǒ ǰǪÀÀ Ü3.4 ǒÀŁÀǤǒǻ

General ǤŋÀŇǒǻ ȣǻÀŇǪèɎǻ ǧǻǿÀǤǪǹǻ" ɈǻƺÀ3 ǨƠ ȣƺȍƺʈǻ ÛB Ō3ÀÀǪǒǻ Ōŋ/ȟ 0.05 ÂŁÕÀǪǽ ȯƺŸǂǻ ɄÛŇÀ :C

.(124 ǤɄÀÔǒǻ Û1 ǼŸŎǻ) ǧǻǼÀǿƺŸȮŸǒ ÂǼȶŋ Ō3ÀÀǪÕ "identification tests

.ŌȮÀǪǒǻ 3ŋ °ȳ 169 ǤǽǻÀę ǿÀǮÔǵɎǻ ǵǿǻÀǵ ǤDZǿǻ ŊŸǨ :D

ƂÀȴǻ ǒÀʈǻ ȡŋ Ōŋ 10 Ž ȟ 0.05 ÂŁÕÀǪǽ ȯƺŸǂǻ ɈƺȮÀ ؛**Clarity and colour of solution** ȯƺŸǂǻ Ɉƺǒş ǒÀÀȍ

.ɈƺŸǒǻ ƇǼ3ş ǼŁƺÀȍ R ɈƺǽÀȮǒǻ ǼŁÊÕǕ ɄǝÀÀǵ ȡŋ

.ȟ/ŊŸŋ 2.0 ȡ3 ǼÀÂÀ Ɏ ؛**Sulfated ash** ǨÀŸÊʈǻ ǻÀŋÀǒǻ

0.6 ɁǼŇǪÀ Ɏ) ȐÀǺÀŋ Ȕȣȓ ǨƠ ȔŁǂǻ ǵǿǻÀǵ ǤDZǿǼǽ ƵÀDZƗ ؛**Loss on drying** ƵŁÀDZƺǪǻÀǽ ǼŌÀǒǻ

.ȟ/ŊŸŋ 10 ȡŋ ÀǯÕǕ ǼŌÀÀ Ɏ Üǧ3Àè 4 ǵǼŋ R ǿƺÀÊÀǒǻ ǼŁÊÕǕ ɄèÀȶȟ ȧƺƺ (ȨǤǝǻ ǈŸŋ 5 ǤǽǻÀę şǕ ȯÀȮèÀǽƺŸŁÕ

.6.0 - 4.5 ÛŌŋ/ŊŸŋ 10 ÂŁÕÀǪǽ ȯƺŸǂǻ ǒÀŁÀǽ ŊŸǤÀ ؛**pH value** ǒÀŁÀǤǒǻ ǤȶŁę

Ȑβ ȯƺŸŢ Ž Ōŋ/ŊŸŋ 1.0 ÂŁÕÀǪǽ ȯƺŸŢ ȡŋ ǈè 1 ǤǵÀǺǯǽ ǤŐǤù î ÀǪ ǼÀÂÀ Ɏ ؛**Isoprenalone** ɈƺǒÀÀÀÀǽşÂÀǕ

ǈè 2 ÈŁŌǨ ǧǻǨDZǵ ȳǻǼǺǪèǻ ŌȒÀƗ) 0.2 ȡ3 ÀǪŋƺǵÀǽ 310 ǤDZƺʈǻ ȯƺù Ž VS (ȯ/ȯƺŋ 0.005) ŌÀǿƺÀŸÊǒǻ

.(ǈè 1 ǤǵÀǺǯǽ ǤŐǤÛǒ î ÀȶǪǒǻ ǼÊɄƗş ǟÀŁŌŸǒ

ǼǵǗ ǵǼ3ÀÊŋ R1 ɄDZŸǯǒǻ ŌŁǪèǰǻ Ȑβ ȡŋ Ōŋ 30 Ž ÛǤŁùƺǤȒŋ ǤǵşǻƺŋÛȟ 0.5 ǤǽǻÀę ǟǻǾƗ ؛**Assay** ǤÊÀÀŌʈǻ

Ȑβ ȯƺŸɄŋ ÀÀŇƗş TS ŌŁǪèǰǻ Ȑβ/ȨǤǝÂǒǻ ǧÀǪŁèǕ ȯƺŸŢ ȡŋ Ōŋ 10 ȣÀȒÀ ÛƙǺÊǪǒǻ ȡŋ ɁǿǵǻǕ

Û"Non-aqueous titration ɄǝÀŋŸǒǻ Ȕèƺǒǻ Ž ǵÀÀŇʈǻ" ɈǻƺÀ3 ǨƠ ȣƺȍƺŋ ƺŁ ÀȶÕ VS (ȯ/ȯƺŋ0.1) ŌÀǿƺŸÕǨǤǒǻ

ŊŸŋ 24.77 ȕƺÀȮÀ VS (ȯ/ȯƺŋ 0.1) ŌÀǿƺŸÕǨǤǒǻ Ȑβ ȯƺŸŢ ȡŋ Ōŋ 1 ŌÕ .(142 ǤɄÀÔǒǻ Û1 ǼŸŎǻ) A ǤŐÀÀÛǒǻ

.Û$C_{11}H_{17}NO_3$,HCl ȡŋ

ǏǿǼșƟǁ üƑDŽyƗƨ ǘǁ ǫǷǮŽǁ DžǏǁƑǼǏβǤǸȒǏǕǁ ǫǏβǸǂǀǸβǫǏǉ üǗǓ ɦǏǯƑŢǻ ǀƑǤǂƯŁŽ

Additional requirements for Isoprenaline hydrochloride for parenteral use

.(56 ǤɄÀÔǒǻ Û4 ǼŸŎǻ ÀŢǵǻ) "*Parenteral preparations* ǤŁŌΣǻ ǧǻÀȒɄǪÊʈǻ" ǵǻşÀƺǕ Ž ǻǾş Àʈ ǼŁDZǪÊǨ

øǺǬǹɟǡ" ɉǡƺǺȝ ǨƠ ȣƺǸƺƞ ƺĿ ǺȶǙ øǺǬǹɟǡ ĘǼǕŀ ¦**Bacterial endotoxins** ǦɛƞƺǭǸɕǡ ǦǛǹǡǼǙǡ ğǺǾǺǺØǙǡ
ɟ Ü(ǦǺǼǛƱqǡ ǦǦǦÛǙǡ ȸƞ 30 ǦǶǺÔǙǡ Û5 ǼǛÕǡ) "Test for bacterial endotoxins ǦɛƞƺǭǸɕǡ ǦǛǹǡǼǙǡ ğǺǾǺǺØǙǡ ǬDZɉ
.ȠǛƞ 1 ǬǙ Ž RS ȸǛǹǡǼǙǡ ɉǺǺØǙǡ ȸƞ ǦǙşǻ ǥǼǵş 1250.0 ȸƞ ǸǯǬǙ Ƀƺȝ

ØØØØØ

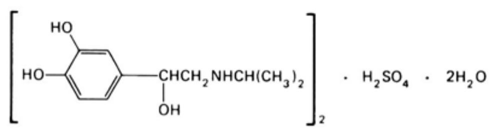
ISOPRENALINI SULFAS

Isoprenaline sulfate DžǏǁǶǏþǦǋȐǏǕɛ ǀ ƑƺǂƨǊɕ

.$(C_{11}H_{17}NO_3)_2,H_2SO_4,2H_2O$ ¦**Molecular formula** ǦǼǺǺȿɕǡ ǦȢǼÔǙǡ

556.6 ¦**Relative molecular mass** ǦǼǦÊǼǙǡ ǦǼǺȿɕǡ ǦǛǬÒǙǡ

¦**Graphic formula** ǦǼǾǺǼǦţǡ ǦȢǼÔǙǡ



¦**Chemical name** ȸǝǺǼȶǼÒǙǡ ǉèɟǡ

3,4-Dihydroxy-α-[(isopropylamino)methyl]benzyl alcohol sulfate (2:1) (salt) dihydrate; 4-[1-hydroxy-2-[(1-methylethyl)amino]ethyl]-1,2-benzenediol sulfate (2:1) (salt) dihydrate; α-[(isopropylamino)methyl]protocatechuyl alcohol sulfate (2:1) (salt) dihydrate; CAS Reg. No. 6700-39-6.

.ǦǶǝǡǸǙǡ ȻǼȝ ÛǼǦǸÕǨ ȐǼǕ şǕ ȐǼǕ Ƀøƺǡǡ ȧƺǶÊƞ ¦**Description** ƵǸƺǙǡ

ǦǙşǽ Ǩȡ ÛTS (ȯ/ȟ750~) ȯƺǾǯǺqǡ Ž ǼǼDZ ɉǺǽşØǙǡ ǦǶǼǶȉ ÛǬǺţǡ Ž ɉǺǽşØǙǡ ǥǺǥ ¦**Solubility** ǦǼǾǺǽşØǙǡ
.R ǨǬɉǡ Ž ɟş R ÿøƺƺşøƺǛȮǙǡ Ž ǼǼǛȶȝ

.Bronchodilator ȸøǦÔę ȝèƺƞ ¦**Category** ǦǺǺǙǡ

.ȯƺȒǙǡ ȸƞ ǦǼȶȚ ÛÿǺȮǵǼǽ ǦǛǛȢƞ ǦǺşǺǥ Ž ǨȯǺǺǺǽşǺqǡ ğǺǺǛè ŞǺǥ Ǽƶ ¦**Storage** ȸǺǺǺǬǙǡ

ȯ ǸǦǬǙǡ ȿǼǙ ǼǼƶøǼǨ ǨȯǺǺǺǸǽşǺqǡ ğǺǺǛè ɉƺǙ (ǻƺÊǺ) ĘȶȢǺ ¦**Additional information** ǦǼƺǺȓǕ ğǺƞƺǛǶƞ
ǡǼȡ Ž ʔøǬǥ ǼǜǸǙǡ Ƀƺɕǡ ȣǤȢǛǙ ȯ ǸǦǬǙǡ ȿǼǙ ǼǼƶøǼǨ ǨȯǺǺǺǸǽşǺqǡ ğǺǺǛè ȭǿǼǬǺş .ȯƺȒǙǡ şǕ ȯǡƺƬǛǙ
.ʔǛȝɉǡ ǥøǡǸΣǡ ğǺDZøǻ Ž ţǸèǕ ȬÒǺǬǙǡ ɉƺÒǺş ÛȯƺȒǙǡ

REQUIREMENTS ƘǦǼǕƱǨǼ!ƒ

ȸȝ ǼȁÂȁ ɝș %98.0 ȸȝ ȪȬȁ ɝ Ȧȵ ɁȲȝ ƙȫȦȁȁÀǝşÂȁqǡ ğȦȀŸȅ ɃȤǪƠ :**General requirement** ÿȦȞȫǡ ÆŸÛǪţǡ
.ǦǂǝȦȵŸȫǡ gåȦţǡ БǕ ţȤǅZÀȫǞǝ ǦǟȤÊȚ Û$(C_{11}H_{17}NO_3)_2,H_2SO_4$ ȸȵ %101.0

:**Identity tests** ƕȉǸǰǁǁǁ ǀ ǫƥƑǦȸǁǫ

350ș ÀǪȵȤȹȦȹ 240 ƙǝ ȝǡȤȵɉǡ ȯǡȤùǕ Ž ǼȽȦÎɫ ȦȵǼȁȝ ÛȬȵ/ȠŸȵ 0.050 ÂǂõÀǪǝ ȯȤŸǂ î ȦÔǪȵɝǡ ȤǂùɃǼǦɫ :A
.0.50 ǦǟǡÀȩ ǡØȽ ǦDZȤţǡ ȯȤù Ž ȴȅ 1 ǦȹȦÁȝǝ ǦȬǦù î ȦǪ ȷȤȮȁ ÜÀǪȵȤȹȦȹ 280 ǦDZȤţǡ ǦǟǡÀȩ ǡǂȽȚȝǕ ǡȍȦÔǪȵǕ ÜÀǪȵȤȹȦȹ
Ǧǝøǡå ȯȤŸȚ ȸȵ Ȭȵ 10 ȦƵǡǼgǕ ɃȤƠ ÛƙǪŸDZȤǵ ȸȵ Ȭõ БǕ Ȭȵ/ȠŸȵ 1.0 ÂǂõÀǪǝ ȯȤŸȚ ȸȵ Ȭȵ 1 ȢȦȒɫ :B
ȦȒȁǕ ȸȮȣ Ü6.4, TS ȫȦȽȦǝ ğǡǝ ğȦȀÊȤ Ǧǝøǡå ȯȤŸȚ ȸȵ Ȭȵ 10 ȜÀȵɉǡ ɃȤƠș Û3.4, TS ȫȦȽȦǝ ğǡǝ ğɝȦȝȤ
gǼȵ øǡÀȬǪȅȒȫ õȦǪɫ ÛVS (ȯ/ȯȤȵ 0.1) åȤǂȫǡ ȯȤŸȚ ȸȵ Ȭȵ 0.5 ȢȦȒɫ .¢ÊȦȹ ȫȦȽȦǦȫǡ ğǡǝ ȜÀȵǕ ğȦǝøǡå ȯȦȽȞǪȅǡ
Ƀǝ ȯȤŸǂǡ Ž ǼȁǼì Àþǃ ȷȤȯ ȷǪȁȁ .VS (ȯ/ȯȤȵ 0.1) ÿȤȁåȤÔȫǡ ğȦȀŸȅȤǂǪ ȯȤŸȚ ȸȵ Ȭȵ 2 ȢȦȒɫș ȨǝȦȩå 5
.(levarterenol ȯȤȁȁƘȋøȦȀǂȫ ȸȝ ǡÂǂǂǪ) 6.4 ȫȦȽȦǦȫǡ Ƀǝ ȯȤŸǂǡ Ž ǼȁǼì ȽDZÊȦȁǝ - Àþǃ ȷȤȯ ȷǪȁȁ Ü 3.4 ȫȦȽȦǦȫǡ
General ǦȵȦȞȫǡ ȢǡÀȞǪȅɝǡ ğǡøȦǦǪȵǡ" ȷǡȤȁȝ ǨƠ ȢȤȍȤţǡ ÛA ȬȝȦÀǪȫǡ Ȭȵ/ȟ 0.05 ÂǂõÀǪǝ ȯȤŸǂǡ ȽÛȞȁ :C
.(123 ǦȞȦÔȫǡ Û1 ǼŸȮǡ) ğȦȀŸÊŸȫ Âǂȹȴ ȬȝȦÀǪõ "identification tests

ƘǪɉǡ ȸȵ Ȭȵ 5 ȢȦȒȁ .ǴǝÀȦɫș ǦȬǂȩå 2 gǼȵ ɁŸǃɫ ÛTS (ȯ/ȟ 750~) ȯȤȹȦȝȁqǡ ȸȵ Ȭȵ 10 Ž ȟ 0.1 ǡǡØɫ :D
ƙȫȦȁȁÀǝşÂȁqǡ ğȦȀŸȅ) °ÿ 162 ǦǟǡÀȩ øȦȚÔȹɝǡ gøǡÀǵ ǦDZøå ȠŸǦƘ ÜȫȦȒǂǝ ǦȁøȤŸǝ ǦǟȦȅƀ ȬȮÎǪƘ ÜǦǵȦìÀȫǡ БǕ R
.(ǦǂǝȦȵŸȫǡ

БȦȵǡ ȫȦţǡ ȸȵ Ȭȵ 10 Ž ȟ 0.40 ÂǂõÀǪǝ ȯȤŸǂǡ ȷȤȮȁ :**Clarity and colour of solution** ȯȤŸǂǡ ȷȤȫș ȫȦȀȍ
.ȷȤŸȫǡ ȻǼȝș ǡȤȦȍ R ȷȤǝÀȮȫǡ ǼǂÊõǕ ȽǝȦȁȹ ȸȵ

.ȟ/ȠŸȵ 2.0 ȸȝ ǼȁÂȁ ɝ :**Sulfated ash** ƘȦŸÊţǡ åȦȵÀȫǡ

Determination of water by ÀÎǂȤ ȯøȦõ ǦȬȁÀÛǝ ȫȦţǡ ƙǂȞƘ" ȷǡȤȁȝ ǨƠ ȢȤȍȤȵ ȤȽ Ȧȶõ ȸǂȞɫ :**Water** ȫȦţǡ
ȸȝ ȪȬȁ ɝ ÜgåȦţǡ ȸȵ ȟ 0.15 ǦǟǡÀȩ ÿǡǼÁǪȅǦǝ Û(145 ǦȞȦÔȫǡ Û1 ǼŸȮǡ) A ǦȬȁÀÛȫǡ Û"the Karl Fischer method
.ȟ/ȠŸȵ 75 ȸȝ ǼȁÂȁ ɝș ȟ/ȠŸȵ 50

5.5 - 4.0 ÛȬȵ/ȠŸȵ 10 ÂǂõÀǪǝ ȯȤŸȚ ȫȦȽȦǝ ȠŸǦȁ :**pH value** ȫȦȽȦǦȫǡ ǦȶǂȘ

Ȓþ ȯȤŸȚ Ž Ȭȵ/ȠŸȵ 1.0 ÂǂõÀǪǝ ȯȤŸȚ ȸȵ ȴȅ 1 ǦȹȦÁȝǝ ǦȬǦù î ȦǪ ǼȁÂȁ ɝ :**Isoprenalone** ȷȤȫȦȁȁÀǝşÂȁǕ
ȴȅ 2 ȄǂȬƘ ğǡƘDZǵ ÿǡǼÁǪȅǡ ȪȒȦɫ) 0.2 ȸȝ ÀǪȵȤȹȦȹ 310 ǦDZȤţǡ ȯȤù Ž VS (ȯ/ȯȤȵ 0.005) ȬȁøȤȦŸÊȫǡ
.(ȴȅ 1 ǦȹȦÁȝǝ ǦȬǦÛȯ î ȦȽǪȫǡ ǼÊȞɫș ǡȦȬŸȯ

ȸȵ Ȭȵ 40ș R1 ȽDZŸȝȫǡ ȬǂǪȅɉǡ Ȓþ ȸȵ Ȭȵ 40 Ž ÛǦǂùȤǦȒȵ Ǧȹşǡȵ Ûȟ 0.45 ǦǟǡÀȩ ǡǡØɫ :**Assay** ǦÊȁȦȬţǡ
ȷǡȤȁȝ ǨƠ ȢȤȍȤȵ ȤȽ ȦȽõ VS (ȯ/ȯȤȵ 0.1) ȬȁøȤŸõƘǦȫǡ Ȓþ ȯȤŸȞȵ ÀȦȁȞɫș acetonitrile R ȬȁÀǪȹȤǪǂȅǕ

1 .(142 1 A "Non-aqueous titration" $(C_{11}H_{17}NO_3)_2,H_2SO_4$ 52.06 VS (0.1)

Additional requirements for Isoprenaline sulfate for parenteral use

.(56 4 "*Parenteral preparations*"

Bacterial endotoxins (30 5) "Test for bacterial endotoxins" RS 1 1250.0.

KALII CHLORIDUM

Potassium chloride

Potassium chloride non-injectable

Potassium chloride for parenteral use

Molecular formula: KCl

Relative molecular mass: 74.55

Chemical name: Potassium chloride; CAS Reg. No. 7447-40-7.

Description:

Solubility: 3 (750~) TS.

Category: Ionic equilibration agent.

Storage:

Labelling:

REQUIREMENTS

General requirement: %99.0

KCl 100.5%

Identity tests:

A: 0.05 2 (~80 g/l) TS
"General identification tests" (123 1).

B: 0.05 A "General identification tests" (123 1).

Heavy metals: 1.0 "Limit test for heavy metals" 1 (127 1) A (128 1) 10 g/l.

Iron: 1.0 "Limit test for iron" (129 1) 40 g/l.

Calcium and magnesium: 20 10 2 TS (~100 g/l) 2 TS (~25 g/l) TS (~40 g/l) 5.

Barium: 0.5 10 R 1 TS (~100 g/l) 1.

Arsenic: 3.3 35 "Limit test for arsenic" (130 1) 3 g/l.

Bromides: 0.08 10 0.25 VS (0.5) 2 TS (15 g/l) tosylchloramide sodium TS R 5 2 (0.119 g/l) TS 9 1.0 10 3 TS

[illegible] "Colour of liquids" [illegible] (53 [illegible] 1 [illegible]).

Iodides : [illegible] 5 [illegible] 25 [illegible] TS ([illegible] 10) [illegible] 2 TS ([illegible] 0.5) [illegible] 2 TS [illegible] 25 [illegible] 5 [illegible].

Sulfates : [illegible] 1.7 [illegible] 20 [illegible] "Limit test for sulfates" [illegible] (125 [illegible] 1 [illegible]) [illegible] 0.3 [illegible].

Clarity and colour of solution : [illegible] 1.0 [illegible] 10 [illegible].

Loss on drying : [illegible] 130 [illegible] 10 [illegible].

Acidity or alkalinity : [illegible] 5.0 [illegible] 50 [illegible] 0.1 [illegible] TS [illegible] 0.2 [illegible] VS ([illegible] 0.02) [illegible] 0.2 [illegible] VS ([illegible] 0.02) [illegible].

Assay : [illegible] 1.0 [illegible] 100 [illegible] 10.0 [illegible] 50 [illegible] 5 [illegible] TS ([illegible] 130~) [illegible] 25.0 [illegible] VS ([illegible] 0.1) [illegible] 2 [illegible] ferric ammonium ([illegible] 45) [illegible] 2.5 [illegible] VS ([illegible] 0.1) [illegible] sulfate TS [illegible] 1 [illegible] VS ([illegible] 0.1) [illegible] KCl 7.455 [illegible].

[illegible]

Additional requirement for Potassium Chloride for parenteral use

[illegible] "*Parenteral preparation*" [illegible] (56 [illegible] 4 [illegible]).

Sodium : [illegible] 589 [illegible] (47 [illegible] 1 [illegible]) [illegible] 1000 [illegible] NaCl 508.4 [illegible] Na 0.2 [illegible] 1 [illegible] 1.0 [illegible].

Baxterial endotoxins : [illegible]

[illegible] 30 [illegible] 5 [illegible] "Test for bacterial endotoxins [illegible] 8.8 [illegible] 1 [illegible] RS [illegible].

[illegible]

Additional requirement for Potassium chloride for steril use

Test for sterility of non- [illegible] "injectable preparations [illegible] 32 [illegible] 5 [illegible].

ØØØØØ

KALII IODIDUM

Potassium iodide [illegible]

KI :**Molecular formula** [illegible]

166.0 :**Relative molecular mass** [illegible]

.Potassium iodide; CAS Reg. No. 7681-11-0 :**Chemical name** [illegible]

[illegible] :**Description** [illegible]

[illegible] 0.7 [illegible] 17 [illegible] (750~ [illegible]) TS. [illegible] 2 [illegible] :**Solubility** [illegible] 75 [illegible] R [illegible] R.

.expectorant [illegible] Antifungal [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] %99.0 [illegible] :**General requirement** [illegible] KI [illegible] %101.0 [illegible].

:**Identity tests** [illegible]

A: [illegible] 0.05 [illegible] 2 [illegible] (80~ [illegible]) TS [illegible] "General identification tests [illegible] 1 [illegible] 123 [illegible]).

General ... 0.05 ... :B
.(122 ... 1 ...) ... "identification tests

... 1.0 ... :**Heavy metals** ...
(127 ... 1 ...) 1 ... "Limit test for heavy metals ...
... 10 ... (128 ... 1 ...) A ...

... 1 ... R ... 10 ... 0.5 ... :**Barium** ...
... 1 ... TS (~100...) ...

... 2 ... R ... 10 ... 0.5 ... :**Iodides** ...
... TS ... 1 ... TS (~100...) ...

... 5 ... 1.0 ... :**nitrites and ammonia** ... **Nitrates** ...
... TS (~80...) ... 5 ... 40 ...
... R ... 0.2
... R ...
... 15 ...

... 20 ... 2.5 ... :**Sulfates** ...
... 0.2 ... (125 ... 1 ...) "Limit test for sulfates ...

... 0.1 ... R ... 10 ... 1.0 ... :**Thiosulfates** ...
... VS (0.01...) ... 0.05 ... TS ...

... 10 ... 1.0 ... :**Clarity and colour of solution** ...

10 ... 105 ... :**Loss on drying** ...

... 0.1 ... R ... 10 ... 1.0 ... :**Alkalinity** ...
... TS ... 1 ... VS (0.05...) ...

Ōņ 50 ȸņ ǰĀĀņ ȸņ Ōņ 10 ȣĀȒĀ .ŏĀţā ȸņ Ōņ 10 Ž ÛĞĒüȤǤȒņ Ǧǫşäȥņ Ûȟ 0.3 ǦäāĀę ā āØł :**Assay** ǦÊĀĀŌţā

ǰǪĀĀ ʔøǪǵ VS (ȯ/ȯȥņ 0.1) ǦȒĀöā ğāĀǪ ȯȥŸĦņ ĀĀĀĤł .TS ȯȥǫĀǯĀ/åȥĒöā ȯȥŸŢ ȸņ ǥĀÛę 1ş TS ĀÎĀöā ȯȥŸŢ ȸņ

.KI ȸņ ŊŸņ 16.60 ùȥĀÒĀ VS (ȯ/ȯȥņ 0.1) ǦȒĀöā ğĀĀǪ ȯȥŸŢ ȸņ Ōņ 1 Ōõ .ǨĿĀæ ĀĀòÛ ȷȥǒ

øøøøø

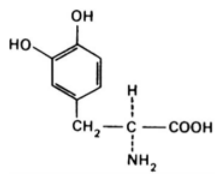
LEVODOPUM

Levodopa ƑǤǊǬǊƻĬǁ

$C_9H_{11}NO_4$:**Molecular formula** ǦĒĀĀÂƨā Ǧ8ĒÔöā

197.2 :**Relative molecular mass** ǦĒǤÊĀöā ǦĒĀĀÂƨā ǦŸǪÒöā

:**Graphic formula** ǦĒǫĀĒǤţā Ǧ8ĒÔöā



:**Chemical name** ɄəĀĒŧĒÒöā ʅèɼā

(–)-3-(3,4-Dihydroxyphenyl)-L-alanine; 3-hydroxy-L-tyrosine;
CAS Reg. No. 59-92-7.

.ǦĦəāĀöā ƇÆȝ ÛĦǤĀĀŎķ ȒĒæÛ ş ȒĒæÛ Ƀøȥǂæ ȧȥĦÊņ :**Description** Ȥòȥā

Ž ɼş ÛTS (ȯ/ȟ750~) ȯȥǫĀǯĀɋā Ž ĀĒŸȶ āāşæ Ƙȡ ÜŏĀţā ȸņ ĀöĀǱ 300 Ž āāşæ:**Solubility** ǦĒǫĀæşØöā

.R ƘǪɉā Ž ɼş R ȳøȥȥşøȥŸÒöā

.Antiparkinsonism drug ǦĒǫȥÊĀõøĀǤŸö åĀȒņ ŏāşå :**Category** ǦĀĀöā

.åøĀæ ȷĀÒņ Ž ȷĀĀĀ ȷÜş ŏȥȒöā ȸņ ǦĒŧŢ ÛȳĀÒǵĀæ ǦŌŸ8ņ ǦĀşĀǵ Ž ĀæşåȥĀĒö ȘĀǵ Æƶ :**Storage** ȸĀÂÁǪöā

REQUIREMENTS ƘǤƕǁƱƙǆ!ƒ

%101.0 ȸȝ ÆĀÂĀ ɼş %98.5 ȸȝ ŌŌĀ ɼ Āņ ʔŸȝ ĀæşåȥĀĒö Ƀȥǫȝ :**General requirement** ȳĀĤöā ÆŸÛǪţā

.ǦĀĀÕā ǥåĀţā Ƀİ ţȥǱĀöĀæ ǦæȥÊŢ Û$C_9H_{11}NO_4$ȸņ

:**Identity tests** ƕĬǊǆǁǁ ǀ ƐƥƑǶǇƐ

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Related substances [illegible]." [illegible] B [illegible] C.

C: [illegible] 5 [illegible] 1 [illegible] 1 [illegible] 5 R [illegible] 4-[illegible]-R 4 [illegible] 3 [illegible] nitrobenzoyl chloride [illegible]. [illegible] 0.1 [illegible] (ό/ȟ200) TS [illegible].

Specific optical rotation [illegible] 0.5 [illegible] VS (ό/όζ 1) [illegible] 5 [illegible] 10 [illegible] 25 [illegible] methenamine R [illegible] 25 [illegible] VS (ό/όζ1) [illegible] 3 [illegible] 25 [illegible] $[a]_D^{20°C} = -160$ to $-167°$ [illegible].

Heavy metals [illegible] 1.0 [illegible] "Limit test for heavy metals [illegible]" [illegible] 3 [illegible] (127 [illegible] 1 [illegible]) A [illegible] (128 [illegible] 1 [illegible]) 10 [illegible].

Clarity and colour of solution [illegible] 0.50 [illegible] 2 [illegible] (ό/ȟ 70~) TS [illegible] 8 [illegible] Yw2 [illegible] "Colour of liquids [illegible]" (53 [illegible] 1 [illegible]).

Sulfated ash [illegible] 1.0 [illegible].

Loss on drying [illegible] 105 [illegible] 10 [illegible].

Related substances [illegible] "Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible]) R2 [illegible] 50 [illegible] 25 [illegible] R [illegible] 25 [illegible] R [illegible]-1 [illegible] 10 [illegible] R [illegible] 5 [illegible] 0.10 [illegible]

[illegible] .B [illegible] 100 [illegible] A [illegible] 0.5 [illegible] .A [illegible] 10 [illegible] R [illegible] 5 [illegible] RS [illegible] 0.10 [illegible] 30 [illegible] .C [illegible] R [illegible] 100 [illegible] 0.5 [illegible] .R [illegible] 1 [illegible] .R [illegible] 100 [illegible] R [illegible] 1 [illegible] R [illegible] 20 C B A [illegible] 10 [illegible] .D [illegible] A [illegible] 1 [illegible] .D [illegible] 2 [illegible] potassium ferricyanide ([illegible] 50) [illegible] 1 TS ([illegible] 25) [illegible] A [illegible] .([illegible] 365) [illegible] TS [illegible] .B [illegible] D [illegible].

[illegible] R [illegible] 5 [illegible] 0.18 [illegible] :**Assay** [illegible] 0.1) [illegible] R [illegible] 25 R1 [illegible] 25 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible] VS ([illegible] 0.1) [illegible] 19.72 [illegible] VS ([illegible] 0.1) [illegible] 1 [illegible] .(131 [illegible] 1 .$C_9H_{11}NO_4$

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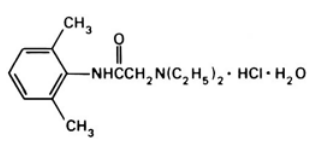
LIDOCAINI HYDROCHLORIDUM

Lidocaine hydrocloride [illegible]

$C_{14}H_{22}N_2O,HCl,H_2O$:**Molecular formula** [illegible]

288.8 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2-(Diethylamino)-2′,6′-acetoxylidide monohydrochloride monohydrate; 2-(diethylamino)-*N*-(2,6-dimethylphenyl)acetamide monohydrochloride monohydrate; CAS Reg. No. 6108-05-0.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] 0.7 [illegible] 1.5 [illegible] (~750 g/l) TS [illegible] R [illegible].

[illegible] **Category**: [illegible] Local anaesthetic.

[illegible] **Storage**: [illegible].

[illegible] **Additional information**: [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 99.0% [illegible] 101.0% [illegible] $C_{14}H_{22}N_2O$, HCl [illegible].

Identity tests [illegible]:

- [illegible] A [illegible] C [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43). [illegible] reference spectrum [illegible].

B: [illegible] 0.15 [illegible] 10 [illegible] (~80 g/l) TS [illegible] 1 [illegible] (~750 g/l) TS [illegible] 0.5 [illegible] TS [illegible] 2 [illegible].

C: [illegible] 0.05 g/ml [illegible] B [illegible] "General identification tests" ([illegible] 1 [illegible] 121).

D: [illegible] 0.1 g [illegible] 10 ml [illegible] 10 ml [illegible] (7 g/l) TS. [illegible] 105 °C [illegible] 230 °C [illegible].

.°[illegible] 79 - 74 :**Melting vange** [illegible]

[illegible] 1.0 [illegible] :**Heavy metals** [illegible] (127 [illegible] 1 [illegible]) 1 [illegible] "Limit test for heavy metals [illegible]" [illegible] (128 [illegible] 1 [illegible]) A [illegible] 10 [illegible].

[illegible] 10 [illegible] 1.0 [illegible] :**Clarity and colour of solution** [illegible].

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible].

Determination of water by [illegible] :**Water** [illegible] (145 [illegible] 1 [illegible]) A [illegible] "Karl Fischer method [illegible] 0.2 [illegible] 75 [illegible] 50 [illegible].

.5.5 - 4.0 [illegible] 0.05 [illegible] :**pH value** [illegible]

[illegible] 4 [illegible] 0.10 [illegible] :**Primary aromatic amines** [illegible] TS [illegible] 70~) [illegible] 100 [illegible] 10 [illegible] R [illegible] 50 [illegible] 10 [illegible] 15 [illegible] R [illegible] 1 [illegible] 10 [illegible] R [illegible] TS [illegible] 80~) [illegible] 2.5 [illegible] 10 [illegible] TS [illegible] 80~) [illegible] 5 [illegible] "Colour of liquids [illegible]" [illegible] (53 [illegible] 1 [illegible]).

10 [illegible] R1 [illegible] 30 [illegible] 0.55 [illegible] :**Assay** [illegible] VS (0.1 [illegible]) [illegible] TS [illegible] (142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible] VS (0.1 [illegible]) 27.08 [illegible] $C_{14}H_{22}N_2O,HCl$ [illegible] 1 [illegible].

[illegible]

Additional requirements for Lidocaine hydrochloride for parenteral use

"*Parenteral preparations*" (56 ... 4 ...).

Bacterial endotoxins ... "Test for bacterial endotoxins" (5 ... 30 ...) ... 1.1 ... RS ... 1 ...

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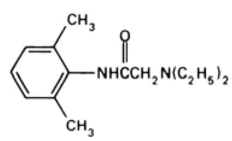
LIDOCAINUM

Lidocaine

Molecular formula: $C_{14}H_{22}N_2O$

Relative molecular mass: 234.3

Graphic formula:



Chemical name:

2-(Diethylamino)-2′,6′-acetoxylidide; 2-(diethylamino)-*N*-(2,6-dimethylphenyl)acetamide; CAS Reg. No. 137-58-6.

Description: ...

Solubility: ... (~750 g/l) TS ... R ... R.

Category: Local anaesthetic.

Storage: ...

Additional information: ...

General requirement: ... 99.0% ... 101.0% ... $C_{14}H_{22}N_2O$ ...

:**Identity tests** ƕĭŇǰŊǁǁɛ ŀ ƐƥƑǴǂƣƐ

.Cş B ȸƖǿǕǬǹɍǟ şǕ ǅǻǞǕƞ A ǿǕǬǹɍǟ ǕƞǕ ȨǕǴÛǩ ȸȮƹ •

ǒǟǞȶΣǟ ǨƠ ǴǨì ɉǟ ǴÔÛǕƞ Ž ɄǝƺȒǟ ƵǕÛǟ âǕȩ" ɈǟƺǕȝ ǨƠ ȣƺòƺƞ ƺȽ ǕȶÕ ȎǂǕǟ ʡȀǅɬ :A

ǨƠ ǴǨì ɉǟ Ž î ǕÔǬƞɍǟ ƵǕù ȨǟǕÛǬ .(43 ǴǂǕÔǟ Û1 ǼǕŎǟ) "Spectrophotometry in the infrared region

.ƙǕǕõşǼǕǕ *reference spectrum* ɄǕǅǕţǟ ƵǕÛǟ ȝƞ şǕ RS ƙǝǕõşǼǕ ȸƞ ǰǬǕ ɃǾǟ ƵǕÛǟ ȝƞ ǒǟǞȶΣǟ

TS ǨǟǕƺȮǟ ǼǕǿƺǕõ ȯƺǕƮ ȸƞ Ōƞ 0.5 ȣǕȒɬ ÛTS (ȯ/ȟ 750~) ȯƺǬǕǬqǟ ȸƞ ȸƞ Ōƞ1 Ž ȟ 0.1 āǟǾɬ :B

.ȧǿǟɉǟ ƃǕ ǴǕǿǕȓ ǒǟǞȒǹ ǴǕèǿ ǰǬǕ ÜǴÕǕȩǻ 2 ǥǼƞ ȒǕǕşȘ

.TS (ȯ/ȟ 7~) ȯƺǕƺşǞǬ ɄǬŸǬ ȸƞ Ōƞ 10 ȣǕȒɬş TS (ȯ/ȟ 750~) ȯƺǬǕǬqǟ ȸƞ Ōƞ 15 Ž ȟ 0.1 āǟǾɬ :C

.(ğǟǕȮǕ) °ÿ 230 ǴǟǞȩ ǿǕƮÔǬɍǟ ǥǿǟǞǵ ǴǅǿǻǕ ƞǕǴǩ .°ÿ 105 ǥǿǟǞǵ ǴǅǿǻǕ Ž ƵǕǅǕşǕ ǒǕţǕǕ ǴǕèǕǟ ŌȆ8ǩ ÛǴǹǞɬ

.°ÿ 69 - 66 :**Melting range** ǿǕƮÔǬqǟ ȯǕƒ

ȯƺǕƮ ȸƞ Ōƞ 4 ȸƞ ǰǕǞƞ Ž ǴǟǾƞ ȟ 1.0 ȯƺǕǂǟ ƘȒǂǬǬ ŌȶǨǬȆɬ :**Heavy metals** ǴǕǕŐǰǟ (ğǟǕŸǕǟ) ɈǻǕǨţǟ

ɃǼΣǟ ǿǕǬǹɍǟ" ɈǟƺǕȝ ǨƠ ȣƺòƺƞ ƺȽ ǕȶÕ ʡǞǅɬş ǒǕţǟ ȸƞ Ōƞ 21ş TS (ȯ/ȟ 750~) ŐǕǿƺǕõşǿǼǕƮǟ Ȑƥ

ǴǕǕŐǰǟ ɈǻǕǨţǟ ʡƺǬƮ ȸǨǨɬ Ü(127 ǴǂǕÔǟ Û1 ǼǕŎǟ) 1 ǒǟǞǅqǟ Û"Limit test for heavy metals ǴǕǕŐǰǟ ɈǻǕǨţǟ ŌǅɉǕ

.ȟ/ÿǟǞɖşǞȮƞ 20 ȸȝ ǼǕǞǕ ɍ Ü(128 ǴǂǕÔǟ Û1ǼǕŎǟ) A ǴÕǕǞÛǟ ȨƺȘ

Ōƞ 20ş TS (ȯ/ȟ 130~) ŐǕǞǬǟ Ȑƥ ȯƺǕƮ ȸƞ Ōƞ2 ȸƞ ǰǕǞƞ Ž ȟ0.50 āǟǾɬ :**Chlorides** ğǟǼǕǿƺǕȮǟ

Limit test ğǟǼǕǿƺǕȮǟ ŌǅɉǕ ɃǼΣǟ ǿǕǬǹɍǟ" ɈǟƺǕȝ ǨƠ ȣƺòƺƞ ƺȽ ǕȶÕ ʡǞǅɬş ǥǿşǞȒǟ ǼǕȝ ǴǹǞɬ ÛǒǕţǟ ȸƞ

.ȟ/ƞŸƞ 0.5 ȸȝ ğǟǼǕǿƺǕȮǟ ʡƺǬƮ ǼǕǞǕ ɍ Ü(124 ǴǂǕÔǟ Û1 ǼǕŎǟ) "for chlorides

ŌȶǨǟ ʡǞǅɬş TS (ȯ/ȟ 70~) ŐǕǿƺǕõşǿǼǕƮǟ Ȑƥ ȯƺǕƮ ȸƞ Ōƞ 5 Ž ȟ0.50 āǟǾɬ :**Sulfates** ğǕǕŸÊǟ

Ü(125 ǴǂǕÔǟ Û1 ǼǕŎǟ) "Limit test for sulfates ğǕǕŸÊǟ ŌǅɉǕ ɃǼΣǟ ǿǕǬǹɍǟ"ɈǟƺǕȝ ǨƠ ȣƺòƺƞ ƺȽ ǕȶÕ

.ȟ/ƞŸƞ 1 ȸȝ ğǕǕŸÊǟ ʡƺǬƮ ǼǕǞǕ ɍ

.ȟ/ƞŸƞ 1.0 ȸȝ ǼǕǞǕ ɍ :**Sulfated ash** ǨǕǕŸÊţǟ ǻǕƞǞǟ

ǴǅǿǻǕ Ž R ǿƺǕÊǕǟ ǼǕÊõǕ ɄèǕȶħ ȧƺƺ ǨǟǕǰǟ ɈǞƺǟ ʡǾǬǵ ƵǕƺ :**Loss on drying** ƵǕǅƺǬǕǟ ǼǕŎǕǟ

.ȟ/ƞŸƞ 5.0 ȸƞ ǞǰõǕ ǼǕŎǕ ɍ ÜȔǕǂǟ ǥǿǟǞǵ

Ȑƥ ȯƺǕƮ ȸƞ Ōƞ 4 Ž ȟ 0.10 āǟǾɬ :**Primary aromatic amines** ǴǕõşɉǟ ǴǕǩǕƞşǿɉǟ ğǕǕǕƞɉǟ

.ɄǅƺŸǬ ÿǕƥ Ž ȯƺǕǂǟ ǻǕǨɬ .ǕȶǅƺǴ ǴǅǿǼƞ Ōƞ 100 ǈǅƺǵ ğǟǕ ǴŸǅƺǵ ÿǟǼǕǬèǕǕ TS (ȯ/ȟ 70~) ŐǕǿƺǕõşǿǼǕƮǟ

ǴŸǅƺΣǟ ƃǕ ȣǕȒɬ .ȯƺǕǂǟ ǻǕǨǕş ǒǕţǟ ȸƞ Ōƞ 10 Ž R ÿƺǕǻƺÔǟ ǨǕǞǬ ȸƞ ƞŸƞ 50 ǿǕǬǹǟ āƺǴǕ Ž āǟǾɬş

ǯÅÅǩ ÛĘǝÅęǻ 10 gǽŋ øäÀÕǪèŸö ÕÅǪǩ .ǻÅǦţä ӯζÅǻζÔöä ǨÀÀǪ ȯζŸȚ ĻDzǵ ȤÔφ ɄDzŸǯöä ӯÅȶΣä Ž gǻζDZζţä ǦääÅę) äÅȣöä ȧŸÛφä ǮÛÕÅÅ ÅŋǼÅȝȿ Û ǻøäÀÕǩ ǦŸDZζΣä ȒÅǺǩ .R ÅÅøζǼöä ȸŋ ȟ1 ȣÅȒǩȿ ɄDzŸǯöä ӯÅȶΣä ȸŋ ǦŸDZζΣä
R ȯζȶǯöä ȸŋ ŊŸŋ 10 ȼǼζ ǡäØţä TS (ȯ/ȟ 80~) ӯζÅǻζÔöä ǼǼÊÕȿøǼǼȽ ȯζŸȚ ȸŋ Ōŋ 2.5 ȣÅȒǩ Û(ǦÕǼęǻ 15 БÜ ȤÅȻȿ ĘǝÅęǻ 10 gǽŋ øäÀÕǪèŸö ÕÅǪǩ ÛTS (ȯ/ȟ 80~) ӯζÅǻζÔöä ǼǼÊÕȿøǼǼȽ ȯζŸȚ ȸŋ Ōŋ 5 ȣÅȒǩ .ÅÕäÅè øÅǪǹɍä ȯζŸȚ ȷζö gǼì ǼÅÅǩ ɍ .ǦòζɄÅţä gǻÅţä ȷȿǻ ȸÒö ÛÅÅφÜ ȣζòζŋ ζȽ ÅȶÕ ǼȽÅì ÅȒɄǩ .ǦŸDZζΣä ĻDzǵ ǦɄÅÔöä Û1 ǼŸŎä) "Colour of liquids ŌǝäζÊöä ȷζö" ȷäζÅȝ ǨƠ ȣζòζŋ ζȽ ÅȶÕ ȷǿÅÕǩ ÅŋǼÅȝ ǼȽÅÎöä ȯζŸȚ ȸȝ .(53

ȯζŸɄŋ ÀÅÅɄȿ ÛɄDzŸǯöä ÕǪǼèɉä Ȓþ ȸŋ Ōŋ 30 Ž ÛǦǼùζǦȒŋ ǦφȿàζŋÛȟ 0.45 ǦääÅę ǡäØǩ :**Assay** ǦÊÅÅÕţä Non-aqueous ɄǝÅŋŸöä Ùèζöä Ž gÅÅɄţä" ȷäζÅȝ ǨƠ ȣζòζŋ ζȽ ÅȶÕ VS (ȯ/ȯζŋ 0.1) ÕÅøζŸÕǨǦöä Ȓþ ùζÅÒÅ VS (ȯ/ȯζŋ 0.1) ÕÅøζŸÕǨǦöä Ȓþ ȯζŸȚ ȸŋ Ōŋ 1 ŌÕ .(142 ǦɄÅÔöä Û1 ǼŸŎä) A ǦÕÅÀÛöä Û"titration .$C_{14}H_{22}N_2O$ ȸŋ ŊŸŋ 23.43

øøøøø

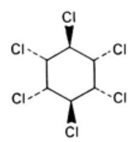
LINDANUM

Lindane DžǦφǻǾ

C_6H_6 Cl_6 :**Molecular formula** ǦǼÅÅÂƨä ǦȣǼÔöä

290.8 :**Relative molecular mass** ǦǼǦÊÅöä ǦǼÅÅÂƨä ǦŸǪÒöä

:**Graphic formula** ǦǼφÅǼǦţä ǦȣǼÔöä



:**Chemical name** ɄǝÅǼȶǼÒöä Ļèɍä

γ-1,2,3,4,5,6-Hexachlorocyclohexane; (1α,2α,3β,4α,5α,6β)-1,2,3,4,5,6-hexachlorocyclohexane; CAS Reg. No. 58-89-9.

Åŋǻȡ ÜGamma benzene hexachloride ǼÅøζŸÕÅÊÒȽ ȸÅÂøÅǽ Åŋǻȡ :**Other name** ÀǹǿÅä Ļèɍä .gammahexachlor cychohexane ȷÅÊÒȽζŸÒǼèøζŸÕÅÊÒȽ

.ǦŸǼŸę ÛǦɄǝäÅöä ÜȒǼǽÜ ȸøζŸǽ ȧζɄÊŋ :**Description** ȤòζöÅ

Åǵ ÛR ǨǪɉȿ R (ȤǼÅƶä) ŏÅţä ţȿÅøÅŋ ȯζφÅǯÅǭä Ž ǡäȿǽ ÜŏÅţä Ž ǼŸȶȝ ǡäȿǽ Ǩȡ :**Solubility** ǦǼφÅǽȿØöä

[illegible] R.

Category: [illegible] Pediculicide [illegible] scabicide.

Storage: [illegible].

General requirement: [illegible] %99.0 [illegible] %100.5 [illegible] $C_6H_6Cl_6$ [illegible].

[illegible] **Identity tests**:

A: [illegible] "Spectrophotometry in the infrared region [illegible] 43) [illegible] RS [illegible] reference spectrum [illegible].

B: [illegible] 1 [illegible] 5.0 [illegible] 3 [illegible] (~750 [illegible]) TS 1 [illegible] TS1 [illegible] 10 [illegible] B [illegible] "General identification tests [illegible] 121).

Congealing temperature [illegible]: [illegible] 112.0 °[illegible].

Free Chlorides [illegible]: [illegible] 1.2 [illegible] 30 [illegible] 1 [illegible] 10 [illegible] (~130 [illegible]) TS [illegible] "Limit test for chlorides [illegible] 124) [illegible] 0.2 [illegible].

Sulfated ash [illegible]: [illegible] 1.0 [illegible].

Water [illegible]: [illegible] Determination of water by [illegible] "Karl Fischer method [illegible] A [illegible] 145) [illegible] 1 [illegible] 5.0 [illegible].

Acidity or lkalinity [illegible]: [illegible] 1.5 [illegible] 30 [illegible] 1 [illegible] 10 [illegible] 2 [illegible] TS [illegible] (0.01 [illegible]) VS [illegible] 0.2 [illegible] 0.4 [illegible] (0.01 [illegible]) VS [illegible] 5 [illegible] TS [illegible].

[illegible] **:Assay** [illegible] 0.4 [illegible] 25 [illegible] (750~ [illegible] TS [illegible] 10 [illegible] (1 [illegible] VS [illegible] 150 [illegible] 10 [illegible] (0.1 [illegible] 50 [illegible] 10 [illegible] (130~ [illegible] TS [illegible] (0.1 [illegible] VS [illegible] VS. [illegible] (45 [illegible] TS [illegible] 1 [illegible] (0.1 [illegible] VS [illegible] 9.693 [illegible] $C_6H_6Cl_6$.

[illegible]

LITHII CARBONAS

Lithium carbonate [illegible]

Molecular formula [illegible]: Li_2CO_3

Relative molecular mass [illegible]: 73.89

Chemical name [illegible]: Dilithium carbonate ; CAS Reg. No. 55-13-2.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] 10 [illegible] (750~ [illegible] TS.

Category [illegible]: Antidepressant.

Storage [illegible]: [illegible].

Additional information [illegible]: [illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] 99.5% [illegible] 100.5% [illegible] Li_2CO_3 [illegible].

Identity tests [illegible]:

A: [illegible] (420~ [illegible] TS [illegible]

[illegible] - [illegible]

B: [illegible] 0.2 [illegible] 5 [illegible] (~420 [illegible]) TS [illegible] 2 [illegible] (~80 [illegible]) TS 5 [illegible] (40 [illegible]) TS [illegible]

C: [illegible] (~70 [illegible]) TS [illegible]

Hezvy metals [illegible] 1.0 [illegible] 10 [illegible] (~60 [illegible]) TS [illegible] 4-3 [illegible] 40 [illegible] "Limit test for heavy metals [illegible] A [illegible] (128 [illegible] 1 [illegible]) 20 [illegible]

Arsenic [illegible] 5.0 [illegible] 15 [illegible] brominated hydrochloric acid AsTS [illegible] 45 [illegible] stannous chloride AsTS [illegible] "Limit test for arsenic [illegible] (130 [illegible] 1 [illegible]) 2 [illegible]

Calcium and magnesium [illegible] 1.0 [illegible] 30 [illegible] (1 [illegible]) VS [illegible] (~100 [illegible]) TS [illegible] 1 [illegible] (25 [illegible]) TS [illegible] 1 [illegible] 5 [illegible] 5 [illegible] (40 [illegible]) TS [illegible]

Chlorides [illegible] 0.35 [illegible] 3 [illegible] (~130 [illegible]) TS 30 [illegible] "Limit test for chlorides [illegible] (124 [illegible] 1 [illegible]) 0.7 [illegible]

Sodium [illegible] (47 [illegible] 1 [illegible]) 589 [illegible] 1000 [illegible] R [illegible] 508.4 [illegible] NaCl (0.2 [illegible] 1 [illegible]) 2.0 [illegible]

[illegible] 3 [illegible] 20 [illegible] 0.5 [illegible] :**Sulfates** [illegible]
Limit test for [illegible] TS [illegible] 250~)
[illegible] 125 [illegible] 1 [illegible] "sulfates

5.0 [illegible] 105 [illegible] :**Loss on drying** [illegible]
[illegible]

[illegible] 50 [illegible] 100 [illegible] 0.75 [illegible] :**Assay** [illegible]
[illegible] VS [illegible] 1) [illegible]
[illegible] 1 [illegible] TS [illegible] VS [illegible] 1) [illegible]
.Li_2CO_3 [illegible] 36.95 [illegible] VS [illegible] 1) [illegible]

[illegible]

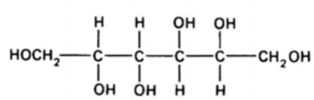
MANNITOLUM

Mannitol [illegible]

$C_6H_{14}O_6$:**Molecular formula** [illegible]

182.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

D-Mannitol; CAS Reg. No. 69-65-8.

[illegible] :**Description** [illegible]

[illegible] TS [illegible] 750~) [illegible] :**Solubility** [illegible]
.R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

%102.0 ... %98.0 ... **General requirement** ... $C_6H_{14}O_6$ ...

Identity tests ...

A: ... 1.0 ... 100 ... 80 ... 50~) ... TS (... 45) ... TS (... (35-32 ... 1 ...) "Determination of specific optical rotation ..."

$[\alpha]_D^{20°C}$ +137 to +145°.

B: ... 0.5 ... 2.5 ... R ... 0.5 ... R ... 60 ... 1 ... 123°...

Melting range ... 165 – 169°...

Heavy metals ... 1 ... (1 ...) "Limit test for heavy metals ..." (128 ... 1 ...) A ... (127 ... 10 ...

Arsenic ... 5.0 ... 35 ... 2 ... (130 ... 1 ...) "Limit test for arsenic ..."

Chlorides ... 2.5 ... 2 ... 130~) TS ... Limit test for ... 30 ... "chlorides ..." (124 ... 1 ...) 0.1 ...

Sulfates ... 5.0 ... 40 ... "Limit test for sulfates ..." (125 ... 1 ...) 0.1 ...

Clarity and colour of solution 1.0 10

Sulfated ash 1.0

Loss on drying 105

5.0

Acidity 5 0.02 0.3

Sorbitol Thin - layer chromatography (84 R1 85 15 2 R 2- A) 750~ 30 10 1 (B) 2 A 1 1

5 110 1 110 0.5 B A

Assay 0.4 100 10 2 R 21.4 20.0 3 15 100~ 0.05 arsenite 25 R 0.05 15 200 R 1.822 0.05 1 0.05

$C_6H_{14}O_6$

[illegible]

Additional requirements for Mannitol for parenteral use

(56 [illegible] 4 [illegible])"*Parenteral preparations* [illegible]

[illegible] **Bacterial endotoxins** [illegible]

[illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible] 1 [illegible] RS [illegible] IU [illegible] 4 [illegible] 1 [illegible] RS [illegible] IU [illegible] 2.5 [illegible] 100 [illegible] 100 [illegible].

ØØØØØ

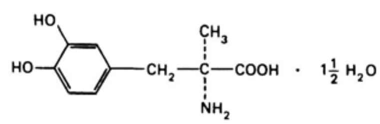
METHYLDOPUM

Methyldopa [illegible]

$H_2O1\frac{1}{2}C_{10}H_{13}NO_4$, 1 ؛**Molecular formula** [illegible]

238.2 ؛**Relative molecular mass** [illegible]

؛**Graphic formula** [illegible]



؛**Chemical name** [illegible]

L-3-(3,4-Dihydroxyphenyl)-2-methylalanine sesquihydrate; 3-hydroxy-α-methyl-L-tyrosine sesquihydrate; CAS Reg. No. 41372-08-1.

[illegible] ؛**Description** [illegible]

[illegible] R [illegible] TS [illegible] 750~) [illegible] ؛**Solubility** [illegible] R [illegible].

[illegible] ؛**Category** [illegible]

[illegible] ؛**Storage** [illegible]

REQUIREMENTS ƘǴǘǐƠǩǳ!ƒ

%101.0 ȸʒ ǼǺǺ ɍȿ %98.5 ȸʒ ǑǬǺ ɍ ǺȠ ʔǛʒ Ǻǽȿǻ ǑǯǮʈǟ Ƀȥǫʒ :**General requirement** ÿǺȞǟ ǼǛÛǪʈǟ
.ǦǲǺȠƔǟ ǵǻǺʈǟ Ɓǚ ʈȥǅǍǾǽ ǦǽȥÊƮ $C_{10}H_{13}N_{14}$ ȸȠ

:**Identity tests** ƕǏǈǋǇǁ Ɩ ƐƥǴǶǇǁ

• ȸǑȿ ǜÛǴ ǖǺȠǚ A ǿǺǪǹɍǟ ȿǚ ǢǻǺǺȠ B ȸǿǺǪǹɍǟ .Cȿ

:A ǖǴǿ Ǒɨǚǟ ȧǼ ǺȶÕ ȣǽȥǹȣ ȝǺǫ ǷƘǑ ȝʔǺʒ "ǚǻǿ ǟǚ ǫǕÛǟ ȤǻRǟ Ž ǦÕÜǠ ǦǼȉǟ ǼǺʈƩǟ ʼnƘǻ ǦǺ

ƘƠ ǦǼȉǟ ǦÛǟ Ž ȋǺÔǪɍǟ ǫǕÛǟ ǖǻǚÛǪ .(43 ǦǼǾÔǟ Û1 ǼǛǑǟ) "Spectrophotmetry in the infrared region

.Ǻǽȿǻ ǑǯǮɞǛǏ *reference spectrum ǸǶǍǺǬǟ ǫǕÛǟ* ʒȠ ȿǚ RS Ǻǽȿǻ ǑǯǮʈǟ ȸȠ ǰǪǺ ɃǾǟ ǫǕÛǟ ʒȠ ǿǺȶʈǟ

"Thin layer Chromatography ǦǑǫǺǟ ǦǑǦÛǟ ǟǻǺΙǪȅǟ" ȝǻǺʒ ƘƠ ȣǽȥǹȣ ȝǺǫ ǺȶÕ ǿǺǪǹɍǟ ǖǴǿ :B

ǺȶǅǴ 25 ÛR ǿȥǫǺȥǽ -1 ȸȠ ǺȶǅǴ 50 ȸȠ ǰǺȠȿ ǦǛǙȠ ǵǻǺȶÕ R2 ǻȥǿȥǛÊǟ ǿǺȶȞǪǻǽ Û(84 ǦǼǾÔǟ Û1 ǼǛǑǟ)

ȸȠ ǺǪǿȿǺǑȠ 5 ǦǼǾÔǟ ʔǛʒ ǛÔǺȠ ǢǴÛǺ .ǑǺǼǪȠ ǿȥÛǑ ǿǺʈǟ ȸȠ ǺȶǅǴ 25ȿ R ɄǅǛǯǟ ǑǮǪèɉǟ ȀƥȸȠ

ǑȠ 1 ǑǑ Ž ǿǺǪǹɍǟ ǵǻǺȠ ȸȠ ȠǛȠ 10 Ƀȥʒ :(A) ǿȥǛǂǟ ÛVS (ǿ/ǿȥȠ 1) ǑǺǿȥǛǑȿǿǼǾǭǟ ȀƥŽ ƘǺǫǟ ƘǿȥǛƮ

ǑǺǪǛ ÛǟǟǺΙǪèɍǟ ǵƘǅǴ ȸȠ ǦǼǾÔǟ ʈǺǫ ǼȞǽ .ǑȠ 1 ǑǑ Ž RS Ǻǽȿǻ ǑǯǮǲȠ ȠǛȠ 10 Ƀȥʒ :(B) ǿȥǛǂǟȿ

25) ǑǺǼǺǼΣǟ ǼǺǿȥǛǑ ǿȥǛƮ ȸȠ ƘǺǫǟ ƘȶǅǴ ȸȠ ǦǿǟȠ ǺǅǟǺȉ ǺRƮ ǿȥǛǾȠ ǽǺǺ Ûȣ ǺǅǍ ǑǟȥǼ ǿǺǮǛ Ž ǦǅǪǿ

.ǿǺƮǺǟ ǑȥȖ Ž ǟǟǺΙǪèɍǟ ǛÛÛ ǑǾǺȿ ÛTS (ǿ/ȟ 50) ÿȥǮèǺǛȥǦǟ ǼǪǺǮè ɃǨȥ ǿȥǛƮ ȸȠ ǺȶǅǴ 1ȿ TS (ǿ/ȟ

.B ǿȥǛǂǟ ȸȠ ǺƮǛǛʒ ǑǑǾǪÊʈǟ ǑǛǩ ʒȠ ǵǼΙǟȿ ǺƮƮʈǟȿ ʒȥȥʈǟ Ž A ǿȥǛǂǟ ȸȠ ǺƮǛǛʒ ǑǑǾǪÊʈǟ ǦǮÊǲǻǺǟ ǦȞǑǦǟ ǢȥǟȥǪǩ

ȸǺÊǽȿ R ǑǺȿǺøǺǽȿǺǪǫǼǺǿȥǛǑ-4 ȸȠ ȠǛȠ 5ȿ ÛR ȸǺǼǺƘǦǟ ȸȠ ǑȠ1 ÛǑǺʈǟ ȸȠ ǑȠ 1 ǿǺǼǑȠ ȠǛȠ 5 Ɓǚ ȣǺRǺ :C

ȿǚ ƃǺǑǞǺǽ ȝȥǿ ǰǪǺ ÛTS (ǿ/ȟ 200) ÿȥǺǻȥÔǟ ǧǺǫȥǽǺǑ ǿȥǛƮ ȸȠ ǑȠ 0.1 ȣǺRǺ ÛȒʅǟ ǑǺǪǚȿ .ȝǺǛǙǟ ʔøǪǴ

.ɄøǫǺȠǺƮǑ

ǼǺǿȥǛǑ ǿȥǛƮ Ž ǿ/ȠǛȠ 44 ǺǮǑǺǪǽ ǿȥǛƮ ǑǺȞǪÊǺ :**Specific optical rotation** Ʉʒȥǟǟ ɃǺÔǦǟ ǺǺȿǼǪǟ

.$[\alpha]_{D}^{20°C}$ -25 to -28° ÛǦǲǺȠƔǟ ǵǻǺʈǟ Ɓǚ ʈȥǅǍǾǽ ǼÊǾǺȿ TS ÿȥǮȠȥǿǂǟ

ƘƠ ȣǽȥǹȣ ȝǺǫ ǿǺǪǹɍǟ ǿȥǛƮ ƘRƠ ǦǮǽ ȟ 1 ǑǺȞǪÊǺ :**Heavy metals** ǦǛǮǑǯǟ (ǧǟǺǛǺǟ) ȝǻǺȞʈǟ

Û(127 ǦǼǾÔǟ Û1 ǼǛǑǟ) 3 ǑǺǅǪǟ Û"Limit test for heavy metals ǦǛǮǑǯǟ ȝǻǺȞʈǟ ǑǅǂɃǼΣǟ ǿǺǪǹɍǟ" ȝǻǺʒ

.ȟ/ÿǟǺȡȿǺǑȠ 10 ȸʒ ǼǺǺ ɍ Û(128 ǦǼǾÔǟ Û1 ǼǛǑǟ) A ǦǑǺÛǟ ǼÊǴ ǦǛǮǑǯǟ ȝǻǺȞʈǟ ʔȥǪƮ ƘȞǺ

.ȟ/ȠǛȠ 1 ȸʒ ǼǺǺ ɍ :**Sulfated ash** ǨǺǛÊʈǟ ǻǺȠǺǟ

Determination of water by ǺΙǼȥ ǿǿǺǑ ǦǑǺÛǽ ǑǺʈǟ ƘǼȞǞ" ȝǻǺʒ ƘƠ ȣǽȥǹȣ ȝǺǫ ǺȶÕ ƘȞǺ :**Water** ǑǺʈǟ

ɍ ŏȦţǟ ʔȥŲŢ ÜgấȦţǟ ȡŋ ȟ 0.2 ĞǟǟȦę ȯȦȶȞŲèȦǣ Û(145 ǴȞȦȍ Û1 ǼŸŎǟ) A ǦŌȦȀÛǟǟ Û"the Karl Fischer method
.ȟ/ŋŸŋ 130 ȡʒ ǼȦȂȦ ɍş ȟ/ŋŸŋ 100 ȡʒ ŌŌȦ

ȀȦȦȞȴş ƘǺÊŲǟǟ gǼʒȦÊŋ R ȷȥǟȀȮǟǟ ǼǢÊõŨ ɄǝȦȦŲ ȡŋ ƃȦʅǟ ŏȦţǟ ȡŋ Ōŋ 100 Ž ȟ 1 ǡǟǾȴ :**Acidity** Ǧȑȥȶ Σǟ
ȡŋ ȀǯõŨ ǼŸÛŲȦ ɍ ÜȀȞÎȶõ TS ȯȥɸȦǯȦŨ/ŌǢǯǢţǟ gȦȶǵ ŌȶȞŲÊȴ ÛVS (ȯ/ȯȥŋ 0.1) ȳȥȦấȥÔǟǟ ǼǢÊõşǿǼǢȽ ȯȥŸȞŋ
.(ƃȦŎǨȦǣ) ȀȞÎȶŸŏ ʔÛèȥǟǟ ǦÛŌȦǟǟ ʔŸʒ ȯȥÔȞŸŏ Ōŋ 0.5

ǡǟȦÎŲèǟ" ȷǟȥȦʒ ǨƠ ȣȥȍȥŋ ȥȽ Ȧȶõ ǿȦǤŲǹɍǟ ĘǤÛȴ :**3-O-Methyl derivative** ŌǢǯǢŋȥɋǿşŨ **3** ĘŲÎţǟ
ȡŋ ǰȦȂŋş ǦŸɸȣŋ gấȦȶõ R ȁȥȯȥŸÊǟǟ ȯȦȶȞŲèȦǣ Û(84 ǴȞȦÔǟǟ Û1ǼŸŎǟ) "Thin layer chromatography ǦŌǢęȀǟǟ ǦŌǤÛǟǟ
ĘǤÛȦ .õȀȞŲŋ ǿȥÛõ ŏȦţǟ ȡŋ ȦȶDzǵ 25ş ÛR ɄDzŸǯǟǟ ŌǢŲǢèɉǟ Ȑþ ȡŋ ȦȶDzǵ 15ş ÛR ȯȥɸȦǩȥǣ -1 ȡŋ ȦȶDzǵ 65
ȳȥDzǵ 4 ȡŋ ǰȦȂŋ Ž ǦǤǝǟǾǟǟ ǿȦǤŲǹɍǟ gấȦŋ ȡŋ Ōŋ/ŋŸŋ 10 ÂǢõȀŲǣ ȯȥŸŢ ȡŋ ȀŲǿşȀȮŋ 10 (A) ǴȞǢȦÔǟǟ ʔŸʒ ȲÔȦȦŋ
50 ÂǢõȀŲǣ ȯȥŸŢ ȡŋ ȀŲǿşȀȮŋ 10 (B) ÛR ȯȥɸȦǯǢţǟ ȡŋ ȦȶDzǵ 96ş TS (ȯ/ȟ250~) ŌȦǿȥŸõşǿǼǢTǟ Ȑþ ȡŋ
(-)-3-(4-hydroxy-3- ƘɸɍŨ ŌǢǯǢŋ –2– (ŌǢǼǢȥ ɄÊõȥǯǢŋ –3– ɄÊõşǿǼǢȽ –4)–3–(–) ȡŋ Ōŋ/ȳǟȀȡşȀȮŋ
.Bş A ƘȯȥŸɉǟ ȡŋ ǦȦşȦÊŲŋ ȳȥDzǵ ȡŋ ǰȦȂŋ ȡŋ ȀŲǿşȀȮŋ 20 (C)ş Ûmethoxyphenyl) -2-methylalanine RS
ÂǢõȀŲǣ ȯȥŸŢ ȡŋ ȳȥDzǵ 5 ȡŋ ǰȦȂŋ ǽȀȴş Ûùȥǟấ ŏǟȥȽ ǿȦǢǩ Ž ȤDzŲǿ õȀŲǩ ǡǟȦÎŲèɍǟ gǨDzǵ ȡŋ ǴȞǢȦÔǟǟ ţȂɸ ǼȞǣ
ǰȦȂŋ Ž ǼǝǟǾǟǟ R ƘŸǢɸŨşȀŲɸ -4 ȡŋ Ōŋ/ŋŸŋ 3 ÂǢõȀŲǣ ȯȥŸŢ ȡŋ ȦȶDzǵ 45ş R ȳȥȦấȥÔǟǟ ǨȦȀŲɸ ȡŋ Ōŋ/ȟ 0.05
ÛùȥǟǼǟǟ ŏǟȥTǟ ȡŋ ǿȦǢǩ Ž ȤȦDzȴ .ŏȦţǟ ȡŋ ȦȶDzǵ 20ş TS (ȯ/ȟ420~) ŌȦǿȥŸõşǿǼǢTǟ Ȑþ ȡŋ ȦȶDzǵ 80 ȡŋ
ɄǿŲǟǟ ǦȞŌǤǟǟ ȷȥȮǩ .ǿȦȾȦǟǟ ŏȥȑ Ž ǡǟȦÎŲèɍǟ ÙÛƯ ȌȞȦȦş ÛTS (ȯ/ȟ 75) ȳȥȦấȥÔǟǟ ǧȦɸȥǟȀõ ȯȥŸȞŋ ǽȀȴ
ÙŌȥ ȦęşǼÔŋ ǿȦǤŲǹɍǟ ƎŲȞȦ .A ȯȥŸɉǟ ȡŋ ǰŲǩ ÛȀȾŢţǟş Ʒęȥţȧǣ ǦŌȥǟȥŲŋ ÛǦȞŌǣ ɃŨ ȡŋ gǼȉ ȀǯõŨ B ȯȥŸɉǟ ȡŋ ǰŲǩ
.dzȥȑȥǣ ƘŲŸÔȦȦŋ ƘŲȞŌǣ C ȯȥŸɉǟ ȡŋ ǰɸ ɃǾǟǟ ǡǟȦÎŲèɍǟ ÙÛƯ ȀȾşŨ ǟǽŨ

20 ȣȦȒȦ ÛR1 ɄDzŸǯǟǟ ŌǢŲǢèɉǟ Ȑþ ȡŋ Ōŋ 20 Ž ÛǦǢùȥǤȒŋ Ǧɸşȁȥŋ Ûȟ 0.20 ĞǟǟȦę ǡǟǾȴ :**Assay** ǦÊȦȦŌţǟ
gȀȦȞţǟ" ȷǟȥȦʒ ǨƠ ȣȥȍȥŋ ȥȽ Ȧȶõ VS (ȯ/ȯȥŋ 0.1) ŌȦǿȥŸõǨǤǟǟ Ȑþ ȯȥŸȞŋ ȀȦȞȦş ÛR ȷȦÊõȥȦǼǟǟ ȡŋ Ōŋ
Ȑþ ȡŋ Ōŋ 1 Ōõ .(142 ǴȞȦÔǟǟ Û1 ǼŸŎǟ) A ǦŌȦȀÛǟǟ Û"Non-aqueous titration ɄǝȦŋŸǟǟ Ùèȥǟǟ Ž
.$C_{10}H_{13}NO_4$ ȡŋ ŋŸŋ 21.12 ùȥȦȮȦ VS (ȯ/ ȯȥŋ 0.1) ŌȦǿȥŸõǨǤǟǟ

ØØØØØ

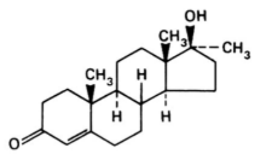
METHYLTESTOSTERONUM

Methyltestosterone DžNjþȞƨNjȾƨȽ üǏǨǏDž

.$C_{20}H_{30}O_2$:**Molecular formula** ǦǢȦȦÂƨǟ Ǧ8ǢÔǟǟ

302.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

17*β*-Hydroxy-17-methylandrost-4-en-3-one; CAS Reg. No. 58-18-4.

[illegible] :**Description** [illegible]

[illegible] TS (750~) [illegible] :Solubility [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %97.0 [illegible] :**General requirement** [illegible] $C_{20}H_{30}O_2$ [illegible] %102.0

:**Identity tests** [illegible]

• [illegible] A [illegible] B [illegible]

A: [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] "Thin layer chromatography [illegible] kieselguhr R1 [illegible] (84 [illegible] 1 [illegible]) [illegible] 10 [illegible] R [illegible] 90 [illegible] R [illegible] 5 [illegible] 16 [illegible]

[illegible] 20 [illegible] R [illegible] 80 [illegible] R [illegible] 9 [illegible] 2 [illegible] .R [illegible] 1 [illegible] :(B) [illegible] 1 [illegible] 1 [illegible] :(A) [illegible] R [illegible] 15 [illegible] 1 [illegible] RS [illegible] -4 [illegible] 15 [illegible] °120 [illegible] 10 [illegible] °120 [illegible] TS [illegible] A [illegible] (365 [illegible]) [illegible]

.B [illegible]

.°165 [illegible] :C

[illegible] 10 [illegible] :**Specific optical rotation** [illegible]

$[\alpha]_D^{20°C}$ + 78 to + 85° [illegible] TS ([illegible] 750~)

([illegible] 750~) [illegible] 10 [illegible] 0.5 [illegible] :**Solution in ethanol** [illegible] Yw2 [illegible] TS

.(53 [illegible] 1 [illegible]) " Colour of liquids [illegible]

10 [illegible] °105 [illegible] :**Loss on drying** [illegible]

[illegible] :**Related Substances** [illegible] R2 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 5 [illegible] R [illegible] 10 [illegible] R [illegible] 90 [illegible] 1 [illegible] 10 [illegible] :(A) [illegible] TS ([illegible] 750~) [illegible] 0.10 [illegible] :(B) [illegible] (254 [illegible]) [illegible]

.B [illegible] A [illegible]

[illegible] TS ([illegible] 750~) [illegible] 20 [illegible] :**Assay** [illegible] 1 [illegible] 100 [illegible] 5 [illegible] 100 [illegible] $C_{20}H_{30}O_2$ [illegible] 242 [illegible]

ȤƐü âǺƐǑɳ Ž âǺǑǺ ǺɳƎǺɜ ÛȖȞƊǺȶ ȯȤŸǂä ɲî ǺǪ ȷȤǾǺ ȷǗ Ǣʑ .ȡɳäǺǪöäȿ ǦǒǺÎȶǺ ǑȞǺǨ ÛRS ȷȿǺǪèȤǪÊǨ
.0.03 ± 0.54 ÛǦǺǺǑǺ ǺƟǨɦ Ȗǝȥ r̀

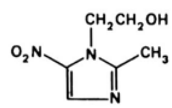
METRONIDAZOLUM

Metronidazole üŇjƦƐơĭǳŇjƥƑǑŽ

$C_6H_9N_3O_3$ ¦**Molecular formula** ǦƐǺǺÂƨä Ǧ8ƐÔöä

171.2 ¦**Relative molecular mass** ǦƐǤÊǺöä ǦƋǺǺÂƨä ǦŸǪǾöä

¦**Graphic formula** ǦƀǺƐǤȼä Ǧ8ƐÔöä



¦**Chemical name** ȖǝǺƐȶƐǾöä ȴèɼä

2-Methyl-5-nitroimidazole-1-ethanol; 2-methyl-5-nitro-1*H*-imidazole-1-ethanol; CAS Reg. No. 443-48-1.

.ǺǤǺǺǑǨ ǦȞǝäǺöä ƇǼɜ ȿǗ ǦȞǝäǺöä ƇǼɜ ÜǢǵǺì ǺǺòǗ ȿǗ R̀ƐǺǗ ÛɃøȤŸǺ ȧȤȞÊɳ ¦**Description** Ȥòȥöä

ÛR ȳøȤȤȿøȤŸǾöäȿ TS (ò/ȟ750~) ȯȤǿǺǯǺɋä Ž ȷǺȿǾöä ǴƐȞì ÜǑǺȶä Ž ȷǺȿǾöä ǬƐŸȩ ¦**Solubility** ǦƐǿǺȿǾöä
.R ƘǪɉäȿ

.ǦǺǺÎǤöä ǥǺǨƐÎȶä åǺȒɳ ÛǦǤƐɳɉä åǺȒɳ ¦**Category** ǦǺǺöä

.ǒȤȒöä ȡɳ ǦƐȶȚ ÛȳǺǾǵǖǺ ǦǬŸ8ɳ ǦǺȿǺǵ Ž ȯȿȁäǢƐǿȿȁǪȼä ȘǺǵ Ǣʑ ¦**Storage** ȡǺÂǺǪöä

ô ǺǨǪöä ƎǺɜ ǺǺÕäá ǴǤÔł ȼǿȤǒ ȡǾǒ ÛǑäȤTä Ž ǨǺǺǪ ȯȿȁäǢƐǿȿȁǪȼä ¦**Additional information** ǦƐȤǺr̀ǗǦ ǧǺɳȤŸȞɳ
.ǒȤȒŸö

REQUIREMENTS ƘǦǝǚƱǩǳ!ƒ

ȡɜ ƎǺÂǺ ɼȿ %99.0 ȡɜ ǑǑǺ ɼ Ǻɳ ɿŸɜ ȯȿȁäǢƐǿȿȁǪȼä ɃȤǪƷ ¦**General requirement** ȳǺȞöä ǢŸÛǪȶä
.ǦǺǺǑä ǥåǺȶä ƂǗ ȶȤǱǺöǺ ǦäȤÊȚ Û$C_6H_9N_3O_3$ ȡɳ%101.0

:**Identity tests** hŭŇjŇĬĬɛ l ɛþƑĠĦĊĬɛ

ŏäÀŁΣä ǨƠ ǴȞìɉä ǴÕÛĄɳ Ž ɄəζŔöä ZƗÛöä âÀƗɕ" ɲäζʒ ǨƠ 8ζòζɳ ζȽ ÀŁõ ÒĦÀöä ĘǴÛÀ :A
ŏäÀŁΣä ǨƠ ǴȞìɉä îÀÔǪɳä ZƗù ĘæÀÛǪÀ .(43 ǴĦÀÔöä Û1ÆŸÕä) "Spectrophotometry in the infrared region
.ȯşäÆƗɸşÀǪƗɫŸö *reference spectrume ɄĦDZÀʈä ZƗÛöä* ʒɳ şÛ RS ȯşäÆƗɸşÀǪƗʈä ZƗù ʒɳ

Ȑþ ȸɳ Ōɳ 0.25ş ÛŏÀʈä ȸɳ Ōɳ 1 ÛR ŌɸÂöä ȧζĦÊɳ ȸɳ ȠŸɳ 10 ȯşäÆĄşÀǪɧ ȠŸɳ 10 БÛ 8ÀŘĄ :B
ȯζŸȚ ȸɳ Ōɳ 0.5 8ÀŘŁ ÛǰŸǯöä Ž ấƎŁ ÛĘəÀɕấ 5 ǵÆɳ ɄəÀɳ ÿÀþ ɁŸʒ ȸǺÊŁş TS (ȯ/ȟ250~) ŌĄøζŸõşøÆƗTä
.TS (ȯ/ȟ 50) ŌƗɳÀĄŸÊöä Ȑþ ȯζŸȚ ȸɳ ǴƗζÀõ ǴƗŁÒæ ÆəäÂöä ǨĄÀǪÀöä ţÂøĄş ÛTS (ȯ/ȟ100) ÿζĄấζÔöä ǨĄÀǪ
ÿζĄấζÔöä ÆƗÊõşøÆƗȽ ȯζŸȚ ȸɳ Ōɳ 2ş TS1 ȯζǯζÀ -2 ȸɳ Ōɳ 0.5 ȸɳ ǰĄÂɳ БÛ ǰǨÀöä ȯζŸǂä ȸɳ Ōɳ 0.5 8ÀŘĄ
.БÀÕǨÀæ – Àþ Û ɲζö ǰǪĄ ÜTS (ȯ/ȟ80~)

.°ÿ163 – 159 :**Melting range** øÀȚÔɸɍä ȯÀƒ

.ȟ/ȠŸɳ 1 ȸʒ ÆĄÂĄ ɍ :**Sulfated ash** ǨÀŸÊʈä ấÀɳÀöä

5.0 ȸɳ Àǯõ Û ÆÕĄĄ ɍ Ü°ÿ 105 ǵøäÀǵ ǴDZøÆæ ǨæÀǯöä ɲàζö ɁøǪǵ ZÀDzŁ :**Loss on drying** ZƗÀDzǪöÀæ ÆÕÀöä
.ȟ/ȠŸɳ

ǴÕƗɕÀöä ǴÕǴÛöä ā äÀÎǪèä" ɲäζʒ ǨƠ 8ζòζɳ ζȽ ÀŁõ øÀǪǹɍä ĘǴÛŁ :**Related substances** ǴöÀÎʈä ấäζʈä
9 ȸɳ ǰĄÂɳş ǴŸɣ8ɳ ǵấÀŁõ R2 ÀÕƗŸƗÊöä ǴɳŸȽ ȯÀŁȞǪèÀæ Û(84 ǴĦÀÔöä Û1 ÆŸÕä) "Thin layer chromatography
ÀǪöşÀÒɳ 5 ǴĦƗÀÔöä ɁŸʒ ɎÔĄɳ ĘǴÛŁ .õÀĦǪɳ øζÛõ R ƙɳÛ ÕƗǯĄÛ ɄəÀĄ ȸɳ ɎŁDzǵ 1ş R ÿøζζşøζŸÒöä ȸɳ ÿζDzǵ
ɲÀõ äæÛ ɎƗŸɕ ȸǺÊŁ) Ōɳ1 Ōõ Ž ǴòζĦÀʈä ǵấÀʈä ȸɳ ȠŸɳ 20 Ƀζʒ :(A) ȯζŸǂä ÛR ɲζǪƗèɍä Ž ƙĄöä ƙȯζŸȚ ȸɳ
ȸɳ ǴĦƗÀÔöä ţÂɸ ÆȞæ .Ōɳ 1 Ōõ Ž ǴòζĦÀʈä ǵấÀʈä ȸɳ ȠŸɳ 0.10 Ƀζʒ :(B) ȯζŸǂäş (ǵấÀʈä Ǵäæɋ ɌĄøşÀȑ Ōöæ
ɍ.(ÀǪɳζɸÀ 254) ɄDzÊÀĄǴöä ȧζζ öζȑ Ž āäÀÎǪèɍä ÙÛƯ ÒĦÀĄş ÛöäζTä Ž ZDzǪö õÀǪǨ Ûā äÀÎǪèɍä ǵƘDzǵ
.B ȯζŸǂä ȸɳ ǰǪǨ ɄøǪöä ŌŸǨ ȸɳ ǵÆì Àǯõ Û ÛǴƗÊƗəÀöä ǴȞŌǴöä ŏÀǯǪèÀæ ÛA ȯζŸǂä ȸɳ ǰǪǨ ǴȞŌæ ǴĄÛ ɲζÒǨ

3 8ÀŘĄ ÛR1 ɄDzŸǯöä ŌƗǪƗèɉä Ȑþ ȸɳ Ōɳ 30 Ž ÛǴƗùζǴŘɳ ǴɸşàζɳÛȟ 0.35 ǴäæÀɕ āäØĄ :**Assay** ǴƗÊĄÀŌʈä
(ȯ/ȯζɳ 0.1) ŌĄøζŸõƘǴöä Ȑþ ȯζŸĦɳ ÀĄÀȞĄş ÀȞÎŁõ T2 ŌƗǪƗèɉä Ȑþ/ƙəÂøÆæ ȯζǪζÀ -1 ȯζŸȚ ȸɳ ȓÀÕɸ
Û1 ÆŸÕä) A ǴÕĄÀÛöä Û"Non-aqueous titration ɄəÀɳŸöä Ùèζöä Ž ǵÀĄÀȞʈä" ɲäζʒ ǨƠ 8ζòζɳ ζȽ ÀŁõ ÛVS
.$C_6H_9N_3O_3$ ȸɳ ȠŸɳ 17.12 ùζÀÒĄ VS (ȯ/ȯζɳ 0.1) ŌĄøζŸõƘǴöä Ȑþ ȸɳ Ōɳ 1 Ōõ .(142 ǴĦÀÔöä

Ĭǳ̌şΘĬɛ üƑDzƴƗƨǘĬ ɱyDZĬɛ üŇjƦɛɱĭǳŇjþƗĎŽĬɛ üɯŬ hŭʒƑȚǝ l ƑǴǂƯƗDž
Additional requirements for Metronidazole for parenteral use
.(36ǴĦÀÔöä Û4ÆŸÕä ÀȚɸä) "*Parenteral preparations* ǴƗÕΣä ǧäÀŘĦǪÊʈä" øæ ǴòÀʅä ǵấşÀζǧä БÛ ÆƗDzǪÊĄ

[illegible] Bacterial endotoxins [illegible] 30 [illegible] "Test for bacterial endotoxins [illegible] 0.35 [illegible] RS [illegible] 1 [illegible].

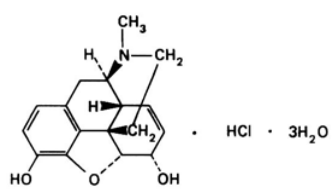
MORPHINI HYDROCHLORIDUM

Morphine hydrochrolide [illegible]

$C_{17}H_{19}NO_3$, HCl, $3H_2O$ ؛**Molecular formula** [illegible]

375.9 ؛**Relative molecular mass** [illegible]

؛**Graphic formula** [illegible]



؛**Chemical name** [illegible]

7,8-Didehydro-4,5α-epoxy-17-methylmorphinan-3,6α-diol hydrochloride (1:1) (salt) trihydrate; CAS Reg. No. 6055-06-7.

[illegible] ؛**Description** [illegible]

[illegible] 25 [illegible] (~750 [illegible]) [illegible] ؛**Solubility** [illegible]

[illegible] R.

[illegible] ؛**Category** [illegible]

[illegible] ؛**Storage** [illegible]

[illegible] ؛**Additional information** [illegible]

[illegible].

REQUIREMENTS [illegible]

[illegible] 98.0% [illegible] ؛**General requirement** [illegible]

... $C_{17}H_{19}NO_3$, HCl ... %101.0 ...

Identity tests

A: ... 5 ... 1 ... 3 ...
... (10 ... TS ... 1 ... (25 ... TS ...

B: ... 5 ... 1 ... 1 ... (60~ ... TS ... 1
... (100~ ... TS ... 1 ... (II) ... (80 ... TS ...

C: ... 1 ... 0.5 ... (1760~ ... TS ...
... TS ...

D: ... 5 ... (70 ... TS
... 1 ... TS2 ... – ...

E: ... 20 ... B ... General
"identification tests ... (121 ... 1 ...)

Specific optical rotaion ... 20 ...
$[\alpha]_{D}^{20°C} = -109° \text{ to } -115°$.

Sulfated ash ... 1.0 ...

Loss on drying ... 105 ... 115
... 150 ...

Acidity ... 0.2 ... 10 ...
... (0.02 ... VS ... TS ... 0.2
...

Meconate ... 0.2 ... 5 ... 5 ... (70~ ... TS
... (25 ... TS ...

Related alkaloids ... 0.5 ... 15
... 2 ... (10 ... TS ... 10 ... R. ...
... R ... 10 ...
... 4 ... (10 ... TS ...

Ōŋ 10 ǤöǍȶǰ̃öä Ƃǚ ȣǺȒł .ȖəǺŋ ÿǺþ ɂŸȝ ȣǺǍƨä ɂøǪǵ óØɰ ǍǺǴǨş ÿóɀɀşóɀŸÒöä ǦǑǤù ǑÔǺǨ .ǥǍŋ Ōõ Ž Ōŋ 5 /ŌǯǮţä ǥǍȶǧ ȯɀŸȚ ȸŋ ǦÛǑǷ 1 ȣǺȒʌ ÛáƎʌ ÛǤææqä ɂøǪǵ ȸǺÊł Ûvs (ȯ/ȯɀŋ 0.01) ȰʌøɀǺŸÊöä Ȓþ ȸŋ Ōŋ 8.75 ȸŋ Ōȩǚ ǼŸÛǪʌ ɏ Üvs (ȯ/ȯɀŋ 0.02) ÿɀʌǻɀÔöä ǼǮÊõşóǼǮȽ ȯɀŸȞŋ Ȓȶ∑ä ǥǻʌä ǍʌǺȞǩş ÛTS ȯɀǺǯʌǚ .(ƃǺǑǨǺæ) ǍȞÎȶŸö ɂÛèɀöä ǦÛǑǺöä ɂŸȝ ȯɀÔȞŸö

ɂŸȝ ȯɀŸǂä ȸǺÊʌş TS (ȯ/ȟ1760~) ȰʌøɀǺŸÊöä Ȓþ ȸŋ Ōŋ 2 Ž ȟ 0.05 ǡäØʌ ¦**Noscapine** ƙæǺÒèɀǺöä .ȖǱÊǺǺæ ȷɀö ǰǪǺʌ ɏ ÜȖəǺŋ ÿǺþ

ȣǺȒʌ ÛR1 ȖǱŸǰöä ȰǮǪǮèɉä Ȓþ ȸŋ Ōŋ 30 Ž ÛǤǮùɀǤȒŋ Ǥǫşàɀŋ Ûȟ 0.3 ǤæäǺȩ ǡäØʌ ¦**Assay** ǦÊǺǺǑţä ɀȽ Ǻȶõ vs (ȯ/ȯɀŋ 0.1) ȰʌøɀŸõǨǤöä Ȓȶɰ ǍʌǺȞǩş ÛTS ȰǮǪǮèɉä Ȓþ/ȨǤəÂöä ǧǺǪǮèǚ ȯɀŸȚ ȸŋ Ōŋ10 .(142 ǦȞǺÔöä Û1ǼŸǑä) A ǦǑʌǍÛöä Û"Non-aqueous titration ȖəǺŋŸöä Ùèɀöä Ž ǥǍʌǺȞţä" ȷäɀǺȝ ǨƠ ȣɀòɀŋ .$C_{17}H_{19}NO_3$,HCl ȸŋ ŊŸŋ 32.18 ȯǻǺȞʌ VS (ȯ/ȯɀŋ 0.1) ȰʌøɀŸõǨǤöä Ȓþ ȸŋ Ōŋ 1 Ōõ

ǏȸȶƟǁɛ üǶǱƴǂƨűǁ ƣƴǷǇǁɛ ǱǏǯþǈǇǁɛ ƣǏþǈǂǀǈþƣǏǉ üɯǓ ǏǳǶȚǻ ƒǂƯǂǇ

Additional requirements for Morphine hydrochloride for parenteral use.

.(56 ǦȞǺÔöä Û4 ǼŸǑä ǍȚǫä) "*parenteral preparations* ǦǮǺǑ∑ä ǧäǺȒȞǪÊţä" øǣ ǦòǺʅä ǥǻşǍɀǥä Ƃǚ ǼǮǱǪÊʌ

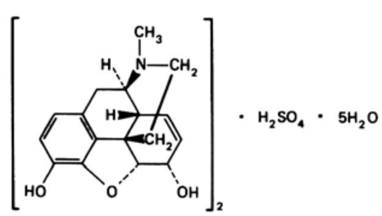
MORPHINI SULFAS

Morphine sulfate ǱǏǯþǈǇǁɛ ǀǶǂƨ

($C_{17}H_{19}NO_3$)$_2$, H_2SO_4, $5H_2O$ ¦**Molecular formula** ǦǮǺʌÂƨä ǦȣǮÔöä

758.8 ¦**Relative molecular mass** ǦǮǤÊǺöä ǦǼǺʌÂƨä ǦŸǪÒöä

¦**Graphic formula** ǦǼǷǺǮǤţä ǦȣǮÔöä



¦**Chemical name** ȖəǺǮȶǮÒöä ɭèɍä

7,8-Didehydro-4,5α-epoxy-17-methylmorphinan-3,6α-diol sulfate (2:1) (salt) pentahydrate; CAS Reg. No. 6211-15-0.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] 20 [illegible] (~750 [illegible]) [illegible]

[illegible] R [illegible] R.

:**Category** [illegible].

:**Storage** [illegible].

:**Additional information** [illegible].

REQUIREMENTS [illegible]

:**General requirement** [illegible] %8.0 [illegible] %101.0 [illegible] $(C_{17}H_{19}NO_3)_2, H_2SO_4$ [illegible].

:**Identity tests** [illegible]

A: [illegible] 5 [illegible] 1 [illegible] 3 [illegible] (10 [illegible]) TS [illegible] (25 [illegible]) TS [illegible].

B: [illegible] 5 [illegible] 1 [illegible] 1 [illegible] (~60 [illegible]) TS [illegible] 1 [illegible] (~100 [illegible]) TS [illegible] (II) (80 [illegible]) TS [illegible].

C: [illegible] 0.5 [illegible] (~1760 [illegible]) TS [illegible] TS [illegible].

D: [illegible] 20 [illegible] A [illegible] "General identification tests [illegible] (1 [illegible] 123).

:**Specific optical rotation** [illegible] 20 [illegible] $[\alpha]_D^{20°C}$ = -106 to -110° [illegible].

:**Sulfated ash** [illegible] 1.0 [illegible].

:**Loss on drying** [illegible] 145 [illegible] 90 [illegible] 120 [illegible].

:**Acidity** [illegible] 0.2 [illegible] 10 [illegible] R [illegible]

[illegible] TS [illegible] VS [illegible] 0.02) [illegible]
.[illegible] 0.2

TS [illegible] 70~) [illegible] 5 [illegible] 5 [illegible] 0.2 [illegible] :**Meconate** [illegible]
.[illegible] TS [illegible] 25) [illegible]

[illegible] 15 [illegible] 0.5 [illegible] :**Related Alkaloids** [illegible]
[illegible] R [illegible] 10 [illegible] TS [illegible] 10) [illegible] 2 [illegible]
[illegible] 10 [illegible] R [illegible]
[illegible] TS [illegible] 10) [illegible] 4 [illegible]
[illegible] 5 [illegible]
[illegible] VS [illegible] 0.01) [illegible] 10 [illegible]
[illegible] VS [illegible] 0.02) [illegible] TS [illegible]
.[illegible] 8.75 [illegible]

[illegible] TS [illegible] 1760~) [illegible] 2 [illegible] 0.05 [illegible] :**Noscapine** [illegible]
.[illegible]

[illegible] R1 [illegible] 30 [illegible] 0.6 [illegible] :**Assay** [illegible]
[illegible] potentionetrically [illegible] VS [illegible] 0.1) [illegible]
[illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible]
.$(C_{17}H_{19}NO_3)_2, H_2SO_4$ [illegible] 66.88 [illegible] VS [illegible] 0.1) [illegible]

[illegible]

Additional requirements for Morphine sulfate for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]" [illegible]

[illegible] :**Bacterial endotoxines** [illegible]
[illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible]
.[illegible] 1 [illegible] RS [illegible] IU [illegible] 14.29 [illegible]

NATRII CHLORIDUM

Sodium Chloride !ǋĭơǋƬǁƐ ơĭƥǋǂǀ

NaCl ¦**Molecular formula** ǦǼǺÂƨǟ Ǧ8ǼÔöä

58.44 ¦**Relative molecular mass** ǦǼǦÊǺöä ǦǼǺÂƨǟ ǦŸǪȮöä

¦**Chemical name** ɄǝǺȾǼȮöä ȴèɼǟ

Sodium chloride; CAS Reg. No. 7647-14-5.

.ǦHɄǝǟǺöä ƇǼȝ ÜȐǼǼǕ Ƀøƺǟǟ ȧƺHÊȠ şǕ ÛȷƺŸöä ǦƸǼȝ ğǟøƺǟ ¦**Description** Ƶòƺöä

.TS (ȯ/ȟ 750~) ȯƺǪǺǯǺɋǟ Ž ȷǺǝşØöä ŌǼŸȩ ÜöǺƫǟ Ž ȷǺǝşØöä Ǻǵ¦**Solubility** ǦǼǪǺǝşØöä

.ɄøǪƺǺǕ Ǧǫǟǟƺȵ ŌȵǺȝ ¦**Category** ǦǺǺöä

.ȳǺȮǵǚǟ ǦŌŸ8ȵ ǦǺşǺǵ Ž ȳƺǺǻƺÔöä ǼǺøƺŸõ ȘǺǵ Ǽƶ ¦**Storage** ȸǺÂǺǪöä

.ǺΣǺȵ ǺęǟØȵ ȳƺǺǻƺÔöä ǼǺøƺŸõ ŌŸƸ ¦**Additional information** ǦǼƺǺȓǕ ğǺȵƺŸȞȵ

REQUIREMENTS ƘǦǻǚƱǩǆ!ƒ

ȸȝ ǼǺÂǺ ɼş %99 ȸȝ ŌŌǺ ɼ Ǻȵ ƻŸȝ ȳƺǺǻƺÔöä ǼǺøƺŸõ ɃƺǪȜ ¦**General requirement** ȳǺȞöä ƔŸÛǪƫǟ .ǦǺǺÕǟ ǥǻǺƫǟ ƂǕ ƫƺǄǺöǺǝ ǦǝƺÊƬ ÛNaCl ȸȵ %100.5

¦**Identity tests** ƕĭǋǊǁƐ ǀƐƥƑǴǭƐ

General ǦȵǺȞöä 8ǟǺȞǪèɼǟ ğǟøǺǪǹǟ" ȷǟƺǺȝ ǨƠ 8ƺòƺȵ ƺȽ ǺȶõȳƺǺǻƺÔöä ŌǄǂ øǺǪǹɼǟ ǼǺȝ :A ǺȒȐɄǼƺ B ŌȝǺǺǪöä öǟǺǄǕ ǟƺŸÛƫǟ ȷǺõ ǟǽǕ .ǥǺȾƫǟ ğƳȝǺǺǪöä ɄÛȞǼƺ (123 ǦɄǺÔöä Û1 ǼŸÕǟ) "identification tests .Ōȵ/ȠŸȵ 20 ǺȾõǺǪǽ ȯƺŸƬ

ǦȵǺȞöä 8ǟǺȞǪèɼǟ ğǟøǺǪǹǟ" ȷǟƺǺȝ ǨƠ 8ƺòƺƫǟ A ŌȝǺǺǪöä Ōȵ/ȠŸȵ 20 ǺȾõǺǪǽ ȯƺŸǂǟ ɄÛȞǺ :B .(121 ǦɄǺÔöä Û1 ǼŸÕǟ) ğǟǼǺøƺŸȮŸö ǺƃƜ ŌȝǺǺǪõ "General identification tests

ǨƠ 8ƺòƺȵ ƺȽ Ǻȶõ øǺǪǹɼǟ ȯƺŸƬ ƘȒƠ ŌǄǂ ȟ 1 ŌȾȞǪÊǺ ¦**Heavy metals** ǦŸǼŌǯöä (ğǟÂŸǺöä) ȷǻǺȞƫǟ Ü(127 ǦɄǺÔöä Û1 ǼŸÕǟ) 1öǟǺǄɋǟ Û"Limit test for heavy metals ǦŸǼŌǯöä ȷǻǺȞƫǟ ŌǄǂ ɃǼΣǟ øǺǪǹɼǟ" ȷǟƺǺȝ .ȟ/ȳǟǺȡşǺȮȵ 10 ȸȝ ǼǺÂǺ ɼ Ü(128 ǦɄǺÔöä Û1 ǼŸÕǟ) A öǟǺǄɋǟ ƔÊǵ ǦŸǼŌǯöä ȷǻǺȞƫǟ ȸȵ ƻƺǪǂǟ ȸȾȞǺ

øǺǪǹɼǟ" ȷǟƺǺȝ ǨƠ 8ƺòƺȵ ƺȽ Ǻȶõ ŌȾȮǩş öǺƫǟ ȸȵ Ōȵ 35 Ž ȟ2.5 ȸȵ ȯƺŸƬ ŌȾȞǪÊǺ ¦**Arsenic** ǸǼǪøÂöä .ȟ/ȳǟǺȡşǺȮȵ 4 ȸȝ ǼǺÂǺ ɼ Ü(130 ǦɄǺÔöä Û1 ǼŸÕǟ) "Limit test for arsenic ǸǼǪøÂöä ŌǄǂ ɃǼΣǟ

[illegible] **Barium** [illegible] 4 [illegible] 20 [illegible] TS (~100) [illegible] 2 [illegible] 30 [illegible] diffused light [illegible].

[illegible] **Calcium and magnesium** [illegible] 20 [illegible] 10 [illegible] 2 [illegible] TS (~100) [illegible] TS (~25) [illegible] TS (~40).

[illegible] **Iodides and bromides** [illegible] 2 [illegible] 3 [illegible] 25 [illegible] TS (~750) [illegible] 1 [illegible] 5 [illegible] TS [illegible].

[illegible] **Iron and Sodium ferrocyanides** [illegible] 0.5 [illegible] 5 [illegible] TS (~100) [illegible] 6 [illegible] 1 [illegible] TS (~70) [illegible] 1 [illegible] TS (~60) [illegible] 2 [illegible] TS (~75) [illegible] A [illegible] B [illegible] 0.4 [illegible] FeTS [illegible] A [illegible] B [illegible] "Colour of liquids [illegible]" (53 [illegible] 1 [illegible]) [illegible] 16 [illegible] Fe [illegible].

[illegible] **Sulfates** [illegible] 1.7 [illegible] 20 [illegible] "Limit test for sulfates [illegible]" (125 [illegible] 1 [illegible]) [illegible] 0.3.

[illegible] **Clarity and colour of solution** [illegible] 1 [illegible] 10 [illegible] R [illegible].

[illegible] **Loss on drying** [illegible] 130 [illegible] 10 [illegible].

[illegible] **Acidity or alkalinity** [illegible] 2 [illegible] 20 [illegible] R [illegible]

0.1 ... 2 ... (0.02) ... 0.2 ... (0.02)

Assay ... 0.25 ... 50 ... 0.1) ... (100 ... 1 ... 5.844 ... NaCl ... (0.1

Additional requirements for sodium chloride for parenteral use

"*parenteral preparation*" (56 ... 4)

Bacterial endotoxins ... "Test for bacterial endotoxins" (5 ... 30) ... 5.0 ... 1

NATRII HYDROGENOCARBONAS

Sodium hydrogen carbonate

Molecular formula: $NaHCO_3$

Relative molecular mass: 84.01

Chemical name:

Monosodium carbonate; CAS Reg, No. 144-55-8.

Other name: Sodium bicarbonate.

Description:

Solubility: (~750)

Category:

Storage:

.ŸĽŸę ĂΛζŸęş ĂΣÀŋ ÄęăØŋ ÿζΛáζÔöăş ƘDZşøÆĽTă ğÀφζăÀõ ÕŸΣ :**Additional information** ĞĽζÀř Ǘ ğÀŋζŸĦŋ
.ÆùÀöă ŏăζTă Ž ŏǙĞă ÕÓÀQΛ ¢ΛÓŏ ÛŏăζTă Ž Ǩ ăÀϙ

REQUIREMENTS ƘĞŵǐƱƙdž!ƒ

Fş %99.0 ÕÖΛ F Àŋ ɁŸ3 ÿζΛáζÔöăş ƘDZşøÆĽTă ğÀφζăÀõ ɃζQ3 :**General requirement** ÿÀĦöă ÆŸÛQţă
.ĞÀÀÖă gåÀţă БǗ ţζDZÀöÀă ĞăζÊŢ Û$NaHCO_3$ ȸŋ %101.0 ȸ3 ÆΛÂΛ

:**Identity tests** ƕĬŇǰŇǁƐ ƖƐƥƑĠĦƢƐ

General ĞŋÀĦöă 8ăÀĦQèFă ğăøÀGQǹă" Jăζ3 ǨƠ 8ζòζŋ ζȽ Àŧõ ÿζΛáζÔöă ÕDZɉ øÀGQǹFă ÆΛ3 :A
ÛÕŧĦQÊţă ζȽ B Õ3ÀÀQöă JÀõ ăæǗ .gÂŧţă ğŸ3ÀÀQöă ɄÛĦΛ ¢φŭζ Û(123 ĞĦÀÔöă Û1 ÆŸÖă) "identification tests
.Õŋ /ŊŸŋ 20 ÂĽõÀQă ȯζŸŢ ÀȒ3

.JζŸöă ĈÆ3 ăÀɖ ĘŸÛΛΛş JăøζζϘÆĦĽζ ǕTS(ȯ/ȟ 70~) ÕΛøζŸõşøÆĽTă ȐƥȸŋĞŸĽŸęĞĽŧõБǗ 8ÀȒΛ :B
.ȐĽăǗ JζŸă ĞăÀèƀ øζÀöă ɁŸ3 ǰQÆĽζ ǕTS ÿζΛáζÔöă ÆĽÊõşøÆĽȽ ȯζŸŢ ȸŋ ğăÀÛę ĞĦȒă 8ÀȒΛ
50) ÿζΛÂøΛ8ţă ğÀΛŸè ȯζŸŢ ȸŋ ğăÀÛę 3Ȓă ĞζÀ8öă gøăÀǵ ĞDZøá Ž Õŋ/ŊŸŋ 20 ÂĽõÀQă ȯζŸŢ БǗ 8ÀȒΛ :C
.ȐĽăǗ JζŸă ĞăÀèƀ ǰQÆĽζ ǕǰΛÂţă ɁŸ8Λ .ĞăÀèƀ ĞΛǗ ǰQΛΛ F ǕTS(ȯ/ȟ

ǨƠ 8ζòζŋ ζȽ Àŧõ øÀGQǹFă ȯζŸŢ ƘȒƠ ÕDZɉ ȟ 1 ÕŧĦQÊΛ :**Heavy metals** ĞŸĽÕǯöă (ğăÂŸÀöă) JáÀĦţă
ĞĦÀÔöă Û1 ÆŸÖă) 1 ĞÕΛÀÛöă "Limit test for heavy metals ĞŸĽÕǯöă JáÀĦţă ÕDZɉ ɃÆΣă øÀGQǹFă" Jăζ3
.ȟ /ÿăÀɖşÀÓŋ 10 ȸ3 ÆΛÂΛ F Ǖ(128 ĞĦÀÔöă Û1ÆŸÖă) A ĞÕΛÀÛöă ÆÊǵ ĞŸĽÕǯöă JáÀĦţă ȸŋ ɁζQǂă ȸĦĦΛ Ǖ(127
ÀƥɉăÈŧÎöă áΛG3 ȧøşùìÀΛöă ăÀ8öă ȯζ3 F ǕøÀGQǹă ǡζGQǗ Ž ȟ 1.0 øăÆÕŋ ȸǺÊƚ :**Ammonium** ÿζĽφζŋɉă
.ȧøăɉă JζŸöă БǗ ÆùÀöă

Jăζ3 ǨƠ 8ζòζŋ ζȽ Àŧõ ÕŧĦöă ÕŧÓΛş ŏÀţă ȸŋ Õŋ 35 Ž ȟ 3.3 ÂĽõÀQă ȯζŸŢ ÕŧĦQÊΛ :**Arsenic** ǸĽφøÂöă
3 ȸ3 ǸĽφøÂöă ɁζQŢ ÆΛÂΛ F Ǖ(130 ĞĦÀÔöă Û1ÆŸÖă) "Limit test for arsenic ǸĽφøÂöă ÕDZɉ ɃÆΣă øÀGQǹFă"
.ȟ/ÿăÀɖşÀÓŋ

ÀŧĽŧɖ ÀǯõɉăɁŸ3 şǗ ĂĽζÀò ȯζŸǂă JζÓĽζ ǕĘăÀęá 5 gÆŋ Õŋ/ŊŸŋ 20 ÂĽõÀQă ȯζŸŢ ɁŸ8ƚ :**Calcium** ÿζĽÊöÀÓöă
.ĂÆDZ ÕĽŸę ÕÓÎă

ȸ3 R JζăÀÓöă ÆĽÊõǕ ɄăÀΛϕ ȸŋ ȯÀǹ ŏÀŋ Ž Õŋ/ŊŸŋ 50 ÂĽõÀQă ȯζŸŢ ŏÀȽÀă ÆΛÂΛ F :**Carbonates** ğÀφζăÀÓöă
.8.6

TS (ȯ/ȟ 130) ÕΛÀQΛöă ȐƥȯζŸŢ ȸŋ Õŋ 2 ȸŋ ǰΛÂŋ Ž ȟ 1.7 øăÆÕŋ ǡăØΛ :**Chlorides** ğăÆΛøζŸÓöă

Limit test for [illegible] 40 [illegible]

"chlorides [illegible] (124 [illegible] 1 [illegible]) 0.15 [illegible] .

[illegible] Sulfates [illegible] 2.5 [illegible] 40 [illegible] 1 [illegible]

Limit test for [illegible] (250~ [illegible]) TS [illegible]

"sulfates [illegible] (125 [illegible] 1 [illegible]) 0.2 [illegible] .

[illegible] 0.50 [illegible] 10 [illegible] **Clarity and colour of solution** [illegible]

[illegible] .

[illegible] **Loss on drying** [illegible]

[illegible] 2.5 [illegible] .

0.2) [illegible] 50 [illegible] 0.5 [illegible] **Assay** [illegible]

[illegible] 1 [illegible] TS [illegible] 3 [illegible] VS [illegible]

$NaHCO_3$ [illegible] 16.80 [illegible] VS [illegible] 0.2) .

[illegible]

Additional requirements for sodium hydrogen carbonate for parenteral use

.(36 [illegible] 4 [illegible]) "*parenteral preparations* [illegible]

[illegible] **Bacterial endotoxins** [illegible]

[illegible] (30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible]

[illegible] 5.0 [illegible] IU [illegible] RS [illegible] 1 [illegible] .

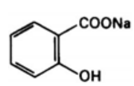
NATRII SALICYLAS

Sodium salicylate [illegible]

$C_7H_5NaO_3$ **Molecular formula** [illegible]

160.1 **Relative molecular mass** [illegible]

Graphic formula [illegible]



Chemical name

Sodium 2-hydroxybenzoate; CAS Reg. No. 54-21-7.

Description

Solubility (~750 TS)

Category

Storage

Additional information

REQUIREMENTS

General requirement 99.0% ... 101.0% $C_7H_5NaO_3$

Identity tests

A: "General identification tests" (123 ... 1) ... B ... 20

B: 0.05 ... "General identification tests" (123 ... 1)

Heavy metals 2.0 ... 45 ... 40 ... 25 ... (~70 TS) ... 5 ... "Limit test for heavy metals" A (128 ... 1) ... 20

Chlorides 1.25 ... 5 ... 5 ... (~710 TS) ... (~1000 TS) ... 1 ... "Limit test for chlorides" (124 ... 1)

[illegible] 0.2 [illegible].

Sulfates: [illegible] 0.85 [illegible] 20 [illegible] 1 [illegible] (250~ [illegible]) [illegible] "Limit test for sulfates" [illegible] (125 [illegible]) [illegible] 0.6 [illegible].

Sulfites and thiosulfates: [illegible] 1 [illegible] 20 [illegible] 1 [illegible] (250~ [illegible]) [illegible] (0.05 [illegible]) VS [illegible] 0.15 [illegible].

Clarity and colour of solution: [illegible] 1.0 [illegible] 10 [illegible] Rd1 [illegible] "Color of liquids" [illegible] (53 [illegible]).

Loss on drying: [illegible] 105 [illegible] 5.0 [illegible].

Acidity: [illegible] 2 [illegible] 50 [illegible] R [illegible] 10 [illegible] (0.1 [illegible]) VS [illegible] 0.2 [illegible].

Assay: [illegible] 0.3 [illegible] 30 [illegible] R1 [illegible] (0.1 [illegible]) VS [illegible] "Non aqueous titration" A [illegible] (142 [illegible]) [illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 10.01 [illegible] $C_7H_5NaO_3$.

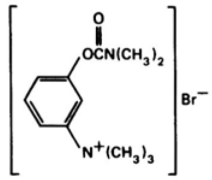
NEOSTIGMINI BROMIDUM

Neostigmine bromide [illegible]

Molecular formula: $C_{12}H_{19}BrN_2O_2$

Relative molecular mass: 303.2

Graphic formula [illegible]



Chemical name [illegible]

(*m*-Hydroxyphenyl)trimethylammonium bromide dimethylcarbamate; 3-[[(dimethylamino)carbonyl]oxy]-*N*,*N*,*N*-trimethylbenzenaminium bromide; CAS Reg. No. 114-80-7.

Description [illegible].

Solubility [illegible] TS (~750 g/l) [illegible] R [illegible].

Category [illegible].

Storage [illegible].

REQUIREMENTS [illegible]

General requirement [illegible] 98.0% [illegible] 101.0% [illegible] $C_{12}H_{19}BrN_2O_2$ [illegible].

Identity tests [illegible]

A: [illegible] 0.05 g [illegible] 0.4 g [illegible] R [illegible] 2 ml [illegible] TS (~750 g/l) [illegible] 3 [illegible] 2 ml [illegible] 2 ml [illegible] diazobenzene-disulfonic acid TS [illegible].

B: [illegible] 0.1 g [illegible] 5 ml [illegible] 15 ml [illegible] TS (7 g/l) [illegible] 105 °C [illegible] 185 °C ([illegible]).

C: [illegible] 20 mg/ml [illegible] A [illegible] General identification tests [illegible] (120 [illegible]).

Sulfates [illegible] 2.5 g [illegible] 40 ml [illegible] Limit test for sulfates ([illegible] 125) [illegible] 0.2 mg/g.

Sulfated ash 1.5

Loss on drying 105 20

Acidity 0.2 20 7 (0.02) 0.1

3-Hydroxy phenyltrimethylammonium bromide -3 5.0 10 TS 1 294 0.2 2 1

Assay 0.25 20 R1 5 TS 10 "Non - aqueous titration" VS 0.1 1 30.32 0.1 A 142 $C_{12}H_{19}BrN_2O_2$

NICLOSAMIDUM

Niclosamide

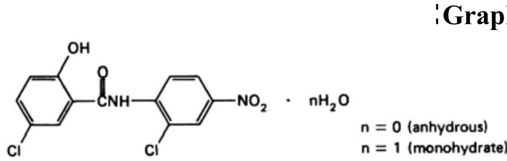
Anhydrous

monohydrate

Molecular formula $C_{13}H_8Cl_2N_2O_4$, $C_{13}H_8Cl_2N_2O_4,H_2O$

Relative molecular mass 327.1 , 345.1

Graphic formula



Chemical name

2′,5-Dichloro-4′-nitrosalicylanilide; 5-chloro-*N*-(2-chloro-4-nitrophenyl)-2-hydroxybenzamide; CAS Reg. No. 50-65-7 (anhydrous).
2′,5-Dichloro-4′-nitrosalicylanilide monohydrate; 5-chloro-*N*-(2-chloro-4-nitrophenyl)-2-hydroxybenzamide monohydrate; CAS Reg. No. 73360-56-2 (monohydrate).

Description:

Solubility: 150 ... (~750 g/l) TS ... R ... R ... R.

Category:

Storage:

Labelling:

Additional information:

REQUIREMENTS

General requirement: 98.0% ... 100.5% ... $C_{13}H_8Cl_2N_2O_4$.

Identity tests:

- A ... B ... C.

A: ... "Spectrophotometry in the infrared region" (1 ... 43). ... *reference spectrum* ...

B: 1 ... 2 ... R ... TS1.

C: 0.1 ... 1 ... R ... 10 ... 10 ... R ... TS (~750 g/l) ... 105 ... 178 ... (...).

Sulfated ash: 1.0 ...

[illegible] **Loss on drying** [illegible] 105 [illegible] 0.5 [illegible] 40 [illegible] 60 [illegible]

[illegible] **Acidity or alkalinity** [illegible] 0.8 [illegible] 40 [illegible] 10 [illegible] 0.2 [illegible] TS [illegible] 0.4 [illegible] TS [illegible] 5 [illegible] VS (0.01 [illegible]) [illegible] VS (0.01 [illegible]) [illegible]

[illegible] **2-chloro -4-nitro aniline** [illegible] 0.1 [illegible] 20 [illegible] R [illegible] 50 [illegible] VS ([illegible]1) [illegible] 10 [illegible] 1.0 [illegible] TS ([illegible] 3) [illegible] 10 [illegible] 1 [illegible] TS ([illegible] 25) [illegible] 1 [illegible] -2 [illegible] 10 [illegible] TS ([illegible] 5) [illegible] (-1) -N [illegible] R [illegible] -4- [illegible] "Colour of liquids [illegible]" [illegible] (53 [illegible] 1 [illegible]).

[illegible] **5-Chlorosalicylic acid** [illegible] 0.5 [illegible] 10 [illegible] TS ([illegible] 25) [illegible]

[illegible] **Assay** [illegible] 0.3 [illegible] 60 [illegible] R [illegible] VS (0.1 [illegible]) [illegible] "Non - aqueous titration [illegible]" B [illegible] 1 [illegible] (142 [illegible]) 1 [illegible] VS (0.1 [illegible]) 32.71 [illegible] $C_{13}H_8Cl_2N_2O_4$.

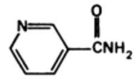
NICOTINAMIDUM

Nicotinamide [illegible]

$C_6H_6N_2O$ **:Molecular formula** [illegible]

122.1 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



Chemical name:

3-Pyridinecarboxamide; 3-pyridinecarboxylic acid amide;
CAS Reg. No. 98-92-0.

Description:

Solubility: (~750) TS

R R.

Category:

Storage:

REQUIREMENTS

General requirement: %99.0 %101.0

$C_6H_6N_2O$

Identity tests:

A B C

A: "Spectrophotometry in the infrared region" (43 1)

RS *reference spectrum*

B: 10 10 2 2

VS (0.1) TS1

(25) TS 3

C: 0.1 1 (~80) TS

Melting range: 128 – 131 °

Heavy metals: 1.0

"Limit test for heavy metals" 1 1

.ȟ/ÿäÀḑşÀÒŋ 30 ȸʒ ÆÂÂ ғ Ü(128 ǦĦÀÔöä Û1 ÆŸŎä) A ǦÕÀÛöä ÆÊǵ ǦŸĔǯöä ɹåÄĦţä ȸŋ ʡʐ ǂ ȸĦĦ Ü(127 ĦĔʐÀò ŏÀţä ȸŋ Ōŋ 10 Ž ȟ 2.5 ÂĔÕÀǪæ ȯʐŸǂä ɹʐÒÀ :**Clarity and colour of solution** ȯʐŸǂä ɹʐǒş ǒÀÀò Ōäʐ Êöä ɹʐǒ "ɹäʐÀʒ ǨƠ ȣʐòʐŋ ʐĿ ÀȶÕ ɹøÀÕƚ ÀŋÆÀʒ Yw2 ɃøÀĔĦţä ɹʐŸöä ȯʐŸȚ ɹʐǒ ȸŋ Ōęǚ ǥÆÎæ ĦǫʐŸŋş .(53 ǦĦÀÔöä Û1 ÆŸŎä) "Colour of liquids

.ȟ/ŋŸŋ 1.0 ȸʒ ÆÂÂ ғ :**Sulfated ash** ǨÀŸÊţä åÀŋÀöä

ғ) ȒÀÁÀŋ Ȕ8ȓ ǨƠ ǦĔöÀʒ ǥøäÀǵ ǦDZøå Ž Ǩæ ÀǯÖä ɹäʐöä ʔøǫǵ ȤÀDZƚ :**Loss on drying** ȤĔÀDZǪöÀæ ÆÕÀöä øʐÀÊÀöä ÆĔÊÕǚ ɄèÀȶȟ ȧʐʐ şǚ ÛÀÒĔŸĔÊöä ǦŋŸĿ ȧʐʐ R ȤǾDZŋ Ž (ĘǤä ǈŸŋ5 Ǧäå Àę şǚ ȯÀÒèÀæʐŸĔÕ0.6 ȸʒ ÆÂÂ .ȟ/ŋŸŋ 5.0 ȸŋ ÀǯÕǚ ÆÕÀÂ ғ ÜR

8.0 – ÛR ɹʐæÀÒöä ÆĔÊÕǚ ɄəÀǫ ȸŋ ȹÀǹ ǒÀŋ Ž Ōŋ/ȟ 0.05 ÂĔÕÀǪæ ȯʐŸǂä ǒÀĿÀæ ŋŸǤ :**pH value** ǒÀĿÀǤöä ǦȶĔę .6.0

ǦÕĔęÀöä ǦÕǤÛöä āäÀÎǫèä" ɹäʐÀʒ ǨƠ ȣʐòʐŋ ʐĿ ÀȶÕ øÀǤǫǹғä ĘǤÛƚ :**Related substances** ǦǒÀÎţä åäʐţä 48 ȸŋ ǰÂÂŋş Ǧǚǰ8ŋ ǥåÀȶÕ R_2 ÀÒĔŸĔÊöä ǦŋŸĿ ȯÀȶĦǫèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸŎä) "Thin layer chromatography ĘǤÛƚ .ÕÀĦǫŋ øʐÛÕ R ǒÀţä ţşÂøÀŋ ȯʐǫÀǯǪä ȸŋ ĦȶDZǵ 45ş ǒÀţä ȸŋ ÿʐDZǵ 10 ÛR ÿøʐʐşøʐŸÒöä ȸŋ ĦȶDZǵ TS (ȯ/ȟ750~) ȯʐǫÀǯǪä ȸŋ ǦÂşÀÊǫŋ ÿʐDZǵ ȸŋ ǰÂÂŋ Ž ƙÀǫä ƙȯʐŸȚ ȸŋ ÀǪşÀÒŋ 5 ǦĦĔÀÔöä ʔŸʒ ŸÔÀÀŋ ǥåÀŋ ȸŋ ŋŸŋ 0.30 Ƀʐʒ :(B) ȯʐŸǂäş Ōŋ 1 ŌÕ Ž øÀǤǫǹғä ǥåÀŋ ȸŋ ȟ 0.12 Ƀʐʒ :(A) ɃşÀΣä ȯʐŸǂä ÛǒÀţäş āäÀÎǫèғä ȔÛƯ ȬĦÀÀş ÛǒäʐȚä Ž ȤDZǫǒ ÕÀǪǩ āäÀÎǫèғä ǥƘDZǵ ȸŋ ǦĦĔÀÔöä ţÂǫ ÆĦæ .Ōŋ 1 ŌÕ Ž øÀǤǫǹғä ǥÆì ÀǯÕǚ ÛǦĔÊĔəÀöä ǦĦÕǤöä ǒÀǯǫèÀæ ÛA ȯʐŸǂä ȸŋ ǰǪǩ ǦĦÕæ ǦǚǚɹʐÒǩ ғ .(ÀǪŋʐǫÀǫ 254) ɄDZÊÀÀǤöä ȧʐʐ ǒʐȒöä Ž .B ȯʐŸǂä ȸŋ ǰǪǩ ɄøǪöä ÕŸǩ ȸŋ

5 ȣÀȒÂ ÛR1 ɄDZŸǯöä ÕĔǪèɉä Ȓþ ȸŋ Ōŋ 20 Ž ÛǦĔùʐǤȒŋ ǦǫşàʐŋÛȟ 2.5 ǦäåÀę āäǾƚ :**Assay** ǦÊÀÀÕţä ǥÀÀĦţä" ɹäʐÀʒ ǨƠ ȣʐòʐŋ ʐĿ ÀȶÕ VS (ȯ/ȯʐŋ 0.1) ÕÀøʐŸÕƘǤöä ȒȶШ ÀÀĦÀş ÛR ÕĔǪèɉä ÆÂøÆŒǚ ȸŋ Ōŋ ÕÂøʐŸÕƘǤöä Ȓþ ȸŋ Ōŋ 1 ŌÕ .(142 ǦĦÀÔöä Û1 ÆŸŎä) A ǦÕÀÛöä "Non-aqueous titration ɄəÀŋŸöä Ȕèʐöä Ž .$C_6H_6N_2O$ ȸŋ ŋŸŋ 12.21 ȕʐÀÒÂ VS (ȯ/ȯʐŋ 0.1)

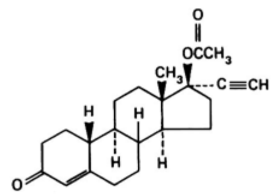
NORETHISTERONI ACETAS

Norethisterone acetate

$C_{22}H_{28}O_3$: **Molecular formula**

340.5 : **Relative molecular mass**

: **Graphic formula**



: **Chemical name**

17-Hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one acetate; 17-(acetyloxy)-19-nor-17α-pregn-4-en-20-yn-3-one; 17α-ethynyl-17-hydroxyestr-4-en-3-one acetate; CAS Reg. No. 51-98-9.

: **Description**

4 TS (750~) 12.5 : **Solubility**

R

: **Category**

: **Storage**

REQUIREMENTS

%97.0 : **General requirement**

$C_{22}H_{28}O_3$ %103.0

: **Identity tests**

A

(43 1) "Spectrophotometry in the infrared region

reference spectrum RS

ǰ ȾøǬ ǦĖĒɚÀ ǦȞȮ ĘƺǽǬ ."Related substances ǦǒÎʈ ǻǽʈ" ɹǽʒ ǨƠ Ȣǭʈ øǹȑɾ ÀȚ :B

.C ȯƺǸɐ ȹ ǰ ȾøǬ ȰǨ ȝȵ ǥÎǯȘ ÛȚʈȘ ÛɀȚ Ž B ȯƺǸɐ ȹ

5 ǥȵ ȾɚȵǸþ Ž VS (ȯ/ȯȵ 0.5) ȯƺɸǙ /ȳǽèǨǽ ǼĒȭȘøǼȽ ȯƺǸʈ ȹ Ȫ 2 ȝȵ ȟ 0.1 ȹǺÊ :C

ȪǮǙ ʓǭ øƺÛ ÜǦȪɕǻ 1 ǥȵ ȤÛǸ ɁǸȘ TS (ȯ/ȟ 700~) ȬøƺǸÊ Ȑþ ȹȪ 2 ȢȐ ÛǻɅ .ĘɚɕǻɁ

.(øǾ ȮȾ ɁǼ) ¢Ǭøȹ¢ȭǻ ȹȮƺ ɃǾ Ûğǭèɉ

ÜR ɹÊȭƺǼ Ž Ȫȵ/ȵ 20 ÂȭÀǬ ȯƺǸʈ ȮȾǸÊ :**Specific optical rotation** ȾȝƺǸ ɃÀÔǦ ÀȘǼǬ

. $[\alpha]_D^{20°C}$ = -32 to -38°

.ȟ/ȵ 1.0 ȹȝ ǼÂ ɍ :**Sulfated ash** ǨǸÊʈ ǻɁȵÀ

5.0 ȹ ǮȭǙ ǼȮ ɍ Ü°ȳ105 ǥøǵ ǦǳøǺ Ž ǨǮǙ ɹȥ ɁøǬǵ ȤǳɁ :**Loss on drying** ȤǼǳǬɁ ǼȮɁ

.ȟ/ȵ

ǦȪÛ ȧÀÎèʼ" ɹǽʒ ǨƠ ȢƺǭȵƺȽ ȾȬ øǹȑɾ ĘǦÛɁ :**Related substances** ǦǒÎʈ ǻǽʈ

ǰÂȘ ǦǸȵ ǥɁȾȬ R1 ÒǼǸÊ ǦȵɎȽ ȯȾǸèɁ Û(84 ǦȾÔ Û1 ǼǸÕ) "Thin-layer chromatographyǦȪɕÀ

ÛÀǬȘÀȮȵ 10 ǦȾÔ ɁǸȝ ɎÔÀȵ ĘǦÛɁ .ȭÀȾǬ øƺÛȭ R ȪǮɍ ğǭèȘ R ȹƺǬ ȹ ǦȘÊǬ ȳƺǳǵ ȹ

ǥɁȵ ȹ ȵǸȵ 10 ɃƺȜ :(A) ȯƺǸɐ ÛR ȳøƺȘøƺǸȮ Ž ȪǼʈ 3 ȹ Ȭȭ ȹ ÛÀǬȘÀȮȵ 5 ȹ ƙȾÊȩ ǼÊǵ

ȵǸȵ 0.10 ɃƺȜ :(C) ȯƺǸɐȘ ÛȪȵ 1 Ȭȭ Ž øǹȑɾ ǥǻȵ ȹ ȵǸȵ 0.10 ɃƺȜ :(B) ȯƺǸɐ ÛȪȵ 1 Ȭȭ Ž øǹȑɾ

ÀǺǬ ɁøǬǵ ȫƺȚ Ž ȤǳǬ ȭÀǬ Û ȧÀÎèɾ ǥǨǳǵ ȹ ǦȾÔ ʈǽ ǼȞ .Ȫȵ 1 Ȭȭ Ž RS ɹøƺǬÊǙøƺǼ ȹ

ÛǦȪɕǻ 15 ǥȵ °ȳ 105 ǥøǵ ǦǳøǺ ɁøǬǵ ǦȾÔ ȹǺÊ .TS ȯƺɸǙ/ȬøƺǸÊ Ȑþ ȯƺǸȾȵ ǼÀȘ Ûğǭøʈ

ǦȞǦ ȫǙèɁ ÛA ȯƺǸɐ ȹ ǰ ǦȮ ǦǙ ɹƺǬ ɍ .øȚǼ ȫƺɩ Ž ȧÀÎèɾ ÙÛƯ ȌȾȘ ÛǻɅǬ ȭǬ

.B ȯƺǸɐ ȝȵ ǰ ȾøǬ ȰǨ ȹ ǥɩ ǮȭǙ ÛǦĒɚÀ

ɁøǬǵ TS (ȯ/ȟ750~) ȯƺɸq ȹ ǦǽȬ ǦȾȬ Ž ÛǦùƺȐȵ ǦȘàƺȵ ÛȵǸȵ 10 ǦÀȩ ȧǾɅ :**Assay** ǦÊȮʈ

ǦȪÛ ȋȾǬ ȃȮɅ .¢ÊɁ ǼǾʈɁ Ȫ 100 Ƃ ȯƺǸɐ ǾȽ ȹȪ 10.0 ȤǺɅ ÜȪ 100 ȴǳǵ ɁǸȝ ȯƺÔƩ

ǥǻʈ Ž $C_{22}H_{28}O_3$ ȹ ǦȾÒ ǼÊƠ .ÀȵƺɁ 240 ǦÀȩ ȾȾȚʒ ǦǳƺȵȯƺùŽ ȤǺʈ ȯƺǸɐ ȹ ȴè1 ǦǺǙ

ȯƺǸȾǸ ȋȾǬ ɹƺÒ ɹ Ǽƶ .ȹȵÀǬȘ ǦǒÎʈɁ ȌȾǨ ÛRS ɹȘǬÊǙøƺǼ ğǭèǙ ȝȵ ǦøȮʈɁ ǦȭƺȾʈ

.0.03 ± 0.51 ǦǺÒɁ ǼȞʈ ȾɚƺȐ ȤǼÛ ȃǼȪȵ Ž ȃȮʈ ȾǳǽÀʈ

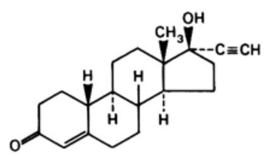
NORETHISTERONUM

Norethisterone [illegible]

$C_{20}H_{26}O_2$:**Molecular formula** [illegible]

298.4 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

17-Hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one; 17α-ethynyl-17-hydroxyestr-4-en-3-one; CAS Reg. No. 68-22-4.

[illegible] :**Description** [illegible]

[illegible] TS (750~) [illegible] 150 [illegible] :**Solubility** [illegible]
R [illegible] 30 [illegible] R [illegible] 80 .

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

%103.0 [illegible] %97.5 [illegible] :**General requirement** [illegible]
$C_{20}H_{26}O_2$ [illegible]

:**Identity tests** [illegible]

[illegible] :A
[illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]).
[illegible] *reference spectrum* [illegible] RS [illegible]
[illegible] ."Related substances [illegible]" [illegible] :B
[illegible] C [illegible] B [illegible].

R [illegible] 10 [illegible] :**Specific optical rotation** [illegible]

$[\alpha]_D^{20°C}$ = -23 to -27°

.ǐ/ŋŶŋ 1.0 ȸ3 ǼǺÂǺ ɽ ׃**Sulfated ash** ǨǺŸÊţä ǻǺŋÀöä

5.0ȸŋ ÀǯõǛ ǼÕǺǺ ɽ Ü°ÿ105 ǥøäÀǵ ǦDZøǻ Ž ǨǼǯöä ɉàɀöä ʔøǫǵ ǮǺDzɫ ׃**Loss on drying** ǮǼǺDzǫöǼǣ ǼÕǺöä .ǐ/ŋŶŋ

ǦÕǼęÀöä ǦÕǤÛöä āäÀÎǫèä" ɉäɀǺ3 ǨƠ 8ɀòɀŋ ɀȽ Ǻɫõ øǺǤǫǹɼä ĘǤÛɫ ׃**Related substances** ǦǒǺÎţä ǻäɀţä 95 ȸŋ ǰǺÂŋş ǦŸǻ8ŋ ǥǻǺɫõ R1 ǺÒǼŸǼÊöä ǦŋɎȽ òǺɫȞǫèǼǣ Û(84 ǦɄǺÔöä Û1 ǼŸǑä) "Thin-layer chromatography ǼÊǵ ÀǫöşÀÒŋ 10 ǦǼɄǺÔöä ʔŸ3 ŸÔǺǺŋ ĘǤÛɫ .õÀɄǫŋ øɀÛõ R òɀǵǺǯǼţä ȸŋ ÿɀDzǵ 5ş R ÿɀɀşøɀŸÒöä ȸŋ ǺɫDzǵ øǺǤǫǹɼä ǥǻǺŋ ȸŋ ŋŶŋ 10 Ƀɀ3 :(A) òɀŸǂä ÛR ÿøɀɀøɀŸÒöä Ž ǦǫɎǯöä ÕǼöǺǂä ȸŋ Ǭõ ȸŋ ÛÀǫöşÀÒŋ 5 ȸŋ ƙɫÊę ȸŋ ŋŶŋ 0.10 Ƀɀ3 :(C) òɀŸǂäş ÛÕŋ 1 Õõ Ž øǺǤǫǹɼä ǥǻǺŋ ȸŋ ŋŶŋ 0.10 Ƀɀ3 :(B) òɀŸǂä ÛÕŋ 1 Õõ Ž ÀǺǤǫǩ ʔøǫǵ ǒäɀȚä Ž ǮDzǫö õÀǫǩ Ûāä ÀÎǫèɼä ǥƘDzǵ ȸŋ ǦɄǼǺÔöä ţÂǫ ǼȞǣ .Õŋ 1 Õõ Ž RS ɉşƘǫÊǼǯǺøɀǺöä õÀǫǩ ÛǦÕǼęǻ 15 ǥǼŋ °ÿ105 ǥøäÀǵ ǦDZøǻ ɃǛ ǦɄǼǺÔöä ȸǺÊǩ .TS òɀǵǺǯǺǛ/ÕǺøɀǺŸÊöä Ȑ þ òɀŸɄŋ ǼÀǩş ÛǧǺǤǺØţä ÛǦǼÊǼǝÀöä ǦȞÕǤöä ǒǺǯǫèǼǣ ÛA òɀŸǂä ȸŋ ǰǫǺǩ ǦȞÕǣ ǦǺǛ ɉɀÒǩ ɽ .øǺȚǺöä ǒɀȉ Ž āäÀÎǫèɼä ÙÛƯ ÒɄǺǺş ÛǻƎǫö .B òɀŸǂä ȸŋ ǰǫǺǩ ɄøǫöäÕŸǩ ȸŋ ǥǼì ÀǯõǛ

òɀÔɄŸö TS (ò/ǐ750~) òɀǵǺǯǺɋä ȸŋ ǦǼɀǺõ Ǧɫõ Ž ÛǦǼùɀǤȒŋ ǦǫşàɀŋÛŋŶŋ 10 ǦäǺę āäØɫ ׃**Assay** ǦÊǺǺÕţä ǦǫøǺǺǯǼǣ ǦÕǤÛö ÎǺɫǫöä āǺÕɫ .ǼǺØţä ÈǺǺǼǣ Õŋ 100 ɃǛ òɀŸǂä äØȽ ȸŋ Õŋ10.0 ǮǺǺɫ ÜÕŋ 100 ǈDzɰ òɀŸȚ ʔŸ3 3ŋ ǦǫøǺÕţǼǣ øǺǤǫǹɼä ǥǻǺŋ Ž $C_{20}H_{26}O_2$ Ǧɫõ ǼÊɄɫ .ÀǫŋɀǫǺǫ 240 ɄɫȚ3Ǜ ǦDZɀŋ òɀù Ž ǮǺǺţä òɀŸǂä ȸŋ ǈè1 ǮǼÛöä āǼÕŋ Ž āǺÕţä ɄȞDZÀţä òɀŸɄɫŸö ÎǺɫǫöä ɉɀÒǺ ɉǛ ǼƵ .ȸŋäÂǫöäş ǦǒǺÎţǼǣ ǦòɀɄǺţä ÛRS ɉşƘǫÊǼǯǺøɀǺöä .0.03 ± 0.58 ǦǺǺÒǼǣ ÀǼȞţä ɄəɀȒöä

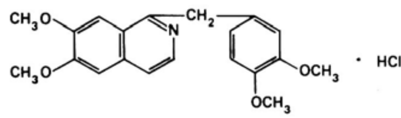
PAPAVERINI HYDROCHLORIDUM

Papaverine hydrochloride

$C_{20}H_{21}NO_4$, HCl ׃**Molecular formula** ǦǼǺǺÂƨä Ǧ8ǼÔöä

375.9 ׃**Relative molecular mass** ǦǼǤÊǺöä ǦǼǺǺÂƨä ǦŸǫÒöä

׃**Graphic formula** ǦǼǫǺǼǤţä Ǧ8ǼÔöä



[illegible] :**Chemical name**

6,7-Dimethoxy-1-veratrylisoquinoline hydrochloride; 1-[(3,4-dimethoxyphenyl)methyl]-6,7-dimethoxyisoquinoline hydrochloride; CAS Reg. No. 61-25-6.

[illegible] :**Description** [illegible].

[illegible] :**Solubility** [illegible] 120 [illegible] (~750 [illegible]) TS [illegible] R [illegible].

[illegible] :**Category** [illegible].

[illegible] :**Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 98.5% [illegible] 101.0% [illegible] $C_{20}H_{21}NO_4$, HCl [illegible].

[illegible] :**Identity tests**

- [illegible] A [illegible] C [illegible] B [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] 1 [illegible] 43). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 10 [illegible] 3 [illegible] 3 [illegible] R [illegible] 3 [illegible] (~1760 [illegible]) TS [illegible] 4–3 [illegible].

C: [illegible] 20 [illegible] B [illegible] General "identification tests" [illegible] 1 [illegible] 121).

D: [illegible] 20 [illegible] 10 [illegible] (~100 [illegible]) TS [illegible] 105°[illegible] 146°[illegible].

.(âǻèɟǟ

БǻɿǟǒǺţǟ ժŋ Ōŋ 10 Ž ȟ0.20 ÂȨõÄǬǣ ȯɀŸȚ ȷɀǾǺ ¦**Clarity and colour of solution** ȯɀŸǂǟ ȷɀǿş ǒǺÀò ɀȽ Ǻȶõ ȷøǺŌǺ ǺŋǼǺȝ Gn2 ɃøǺȨȞţǟ ȷɀŸǟǟ ȯɀŸȚ ȷɀǿ ժŋ ŌęǗ ǥǼÎǣ ǺȱɀŸŋş ǺȨɀǺò R ȷɀǟÀǾǟǟ ǼȨÊõşǗ ƟǝǺǺǬ ժŋ .(53 ǦȞǺÔǟǟ Û1 ǼŸŎǟ) "Colour of liquids ŌǝǟɀÊǟǟ ȷɀǿ" ȷǟɀǺȝ ǨƠ ȣɀòɀŋ

.ȟ/ŋŸŋ 1.0 ժȝ ǼǺÂǺ ȑ ¦**Sulfated ash** ǨǺŸÊţǟ ǻǺŋÀǟǟ

10 ժŋ ÀǯõǗ ǼŌǺǺ ȑ Û°ÿ105 ǥøǟÀǵ ǦDZøǻ Ž ǨǣǺǯǟǟ ȷàɀǟǟ ʔøǬǵ ƵǺDzł ¦**Loss on drying** ƵȨǺDzǬǿǺǣ ǼŌǺǟǟ .ȟ/ŋŸŋ

.4.5 – 3.0 ÛŌŋ/ŋŸŋ 20 ÂȨõÄǬǣ ȯɀŸȚ ǒǺȽǺǣ ŋŸǤǺ ¦**pH value** ǒǺȽǺǤǟǟ ǤȶȨę

ǦŌȨęÀǟǟ ǦŌǤÛǟǟ āǟÀÎǬèǟ" ȷǟɀǺȝ ǨƠ ȣɀòɀŋ ɀȽ Ǻȶõ øǺǤǬǹɼǟ ĘǤÛł ¦**Related substances** ǦŏǺÎţǟ ǻǟɀţǟ 7 ժŋ ǰǺÂŋş ǦŸǿȣŋ ǥǻǺȶõ R2 ǺŌȨŸȨÊǟǟ ǦŋŸȽ ȯǺȶȞǬèǺǣ Û(84 ǦȞǺÔǟǟ Û1 ǼŸŎǟ) "Thin-layer chromatography ĘǤÛǺ .õÀȞǬŋ øɀÛõ R ƙŋǗ ŌȨǯǺǗ ƟǝǺǺǬ ժŋ ǺȨǵǟş ǺȶDzǵş ÛR ŌȨǯǺɋǟ ğǺǬȨèǗ ժŋ ƙȶDzǵ ÛR ժǺɀǿɀǬǟǟ ժŋ ÿɀDzǵ ŌǺøɀŸõşøǼȨTǟ Ȓþ ȯɀŸȚ ժŋ ÿɀDzǵ 4 ժŋ ǰǺÂŋ Ž ƙǿɀŸǂǟ ժŋ Ōõ ժŋ ÀǬǿşÀǾŋ 10 ǦȞȨǺÔǟǟ ʔŸȝ ǺŸÔǺǺŋ øǺǤǬǹɼǟ ǥǻǺŋ ժŋ ȟ 0.05 ɃɀǬȜ :(A) ȯɀŸǂǟ ÛTS (ȯ/ȟ750~) ȯɀǬǺǯǺɋǟ ժŋ ǺȨǵǟş ǺȶDzǵş VS (ȯ/ȯɀŋ 0.01) ǥƘDzǵ ժŋ ǦȞȨǺÔǟǟ ţÂǬ ǼȞǣ .Ōŋ 1 Ōõ Ž R ժǺǻɀǾǟǟ ժŋ ŋŸŋ 0.50 ɃɀǬȜ :(B) ȯɀŸǂǟş Ōŋ 1 Ōõ Ž ÙÛƯ ÒȞǺǺş ÛƙŋǗ ŌȨǯǺǗ ƟǝǺǺǬ ǦȞǝǟø õǟøǻǗ ƵęɀǬǺ ʔøǬǵ ùɀǟǼǟǟ ǒǟɀTǟ ժŋ øǺȨǩ Ž øǟÀŌǬèŸǿ õÀǬǩ Ûāǟ ÀÎǬèɼǟ ÛǦȨÊȨǝÀǟǟ ǦȞŌǤǟǟ ǒǺǺǯǬèǺǣ ÛA ȯɀŸǂǟ ժŋ ǰǬǺǩ ǦȞŌǣ ɃǗ ȷɀǾǩ ȑ .(ÀǬŋɀǬǺǬ 254) ǦȨDzÊǺǺǤǟǟ ȧɀɀ ǦȞìɟǟ Ž āǟ ÀÎǬèɼǟ .B ȯɀŸǂǟ ժŋ ǰǬǺǩ ƟøǬǟǟ ŌŸǩ ժŋ ǥǼì ÀǯõǗ

ȣǺȒł ÛR1 ƟDzŸǯǟǟ ŌȨǬȨèɟǟ Ȓþ ժŋ Ōŋ 30 Ž ÛǦȨùɀǤȒŋ ǦǬşàɀŋ Ûȟ 0.35 ǦǟǟÀę āǟǾł ¦**Assay** ǦÊǺǺŌţǟ ɀȽ Ǻȶõ VS (ȯ/ȯɀŋ 0.1) ŌǺøɀŸõƘǤǟǟ Ȓþ ȯɀŸȞŋ ÀǺǺȞş TS ŌȨǬȨèɟǟ Ȓþ/ĘǤǝÂǟǟ ğǺǬȨèǗ ȯɀŸȚ ժŋ Ōŋ10 .(142 ǦȞǺÔǟǟ Û1 ǼŸŎǟ) A ǦŌǺÀÛǟǟ "Non-aqueous titration ƟǝǺŋŸǟǟ Ùèɀǟǟ Ž ǥÀǺǺȞţǟ" ȷǟɀǺȝ ǨƠ ȣɀòɀŋ .$C_{20}H_{21}NO_4$, HCl ժŋ ŋŸŋ 37.59 ùɀǺǾǺ VS(ȯ/ȯɀŋ 0.1) ŌǺøɀŸõƘǤǟǟ Ȓþ ժŋ Ōŋ 1 Ōõ

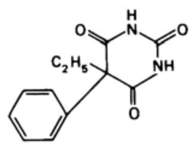
PHENOBARBITALUM

Phenobarbital üƑŦĭĠþƑĜǊǳĩƻǁƐ

.$C_{12}H_{12}N_2O_3$ ¦**Molecular formula** ǦǺǺÂƨǟ ǦȣȨÔǟǟ

232.2 ¦**Relative molecular mass** ǦȨǤÊǺǟǟ ǦǺǺÂƨǟ ǦŸǬǾǟǟ

Graphic formula [illegible]:



Chemical name [illegible]:

5-Ethyl-5-phenylbarbituric acid; 5-ethyl-5-phenyl-2,4,6-(1*H*,3*H*,5*H*)-pyrimidinetrione; CAS Reg. No. 50-06-6.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] 1100 [illegible] 10 [illegible] (~750 [illegible]) [illegible] 15 [illegible] 40 [illegible] R.

Category [illegible]: [illegible].

Storage [illegible]: [illegible].

Additional information [illegible]: [illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] 98.0% [illegible] 101.0% [illegible] $C_{12}H_{12}N_2O_3$ [illegible].

Identity tests [illegible]:

• [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" (1 [illegible] 43). [illegible] *reference spectrum* [illegible].

B: [illegible] 20 [illegible] 5 [illegible] (~750 [illegible]) TS [illegible] cobaltous chloride TS [illegible] (~100 [illegible]) TS [illegible].

C: [illegible] 3 [illegible] 0.1 [illegible] 4 [illegible] (0.1 [illegible]) VS 1 [illegible].

[illegible] 2 [illegible] 4 [illegible] (65 [illegible]) TS [illegible] 5 [illegible] (~100 [illegible]) TS.

ĬKÀÂǪ ȸ ŊŸŊ 10 ĞäàÀę 8ÅȒÀ ÛTS (ȯ/ȟ1760~) ȬÀøȥÀŸÊöä Ȁþ ȯȥŸȚ ȸ Ōŋ 2 Ž ȟ0.1 øäǼŌŋ ǡäØł :D

.ȖøÀǣ ĘÀÀǣ 3ŋ ƂÀŎĶÀǣ – ÀÀòÜ ȷȥö ǰǪǼȥ ÜĘəÀęǻ 10 ǥǼŋ ȖəÀŋ ÿÀþ ʔŸ3 ȸǺÊÀş ÛR ÿȥÀǻȥÔöä

.°ÿ 178 – 174 ¦**Melting range** øÀȚÔǪɍä ȯÀƒ

ÿȥÀǻȥÔöä ǼǼÊȭşøǼȽ ȯȥŸȚ ȸ Ōŋ 4.0 Ž ȟ 1.0 øäǼŌŋ ǡäØł ¦**Solution in alkali** ɃȥŸȬöä Ž ȯȥŸǂä

.ȷȥŸöä ȻǼ3ş ǼȥÀò ȯȥŸǂä ȷȥȮÀ ÜöÀţä ȸ Ōŋ 6.0 8ÅȒÀş TS (ȯ/ȟ80~) ÂǼȭÀǪǣ

ȟ/ŊŸŋ 1.0 ȸ3 ǼÀÂÀ ɍ ¦**Sulfated ash** ĬKÀŸÊţä ǻÀŋÀöä

ȸ ÀǰȭÜ ǼȬÀÀ ɍ Ü°ÿ105 ǥøäÀǵ ĞDZøǻ Ž ĬKäÀǰöä ȷàȥöä ʔøǪǵ ȤÀDzł ¦**Loss on drying** ȤǼADzǪöÀǣ ǼȬÀöä

.ȟ/ŊŸŋ10

8ÅȒł .ǴìÀłş ÛŌŋ 50 ƂÜ ȽDzΣä ȯǼȟł ÛĞŎǼęǻ 2 ǥǼŋ ǒÀţä ȸ Ōŋ 50 3ŋ ȟ 1.0 ʔŸ8ł ¦**Acidity** ĞȑȥȶΣä

ȯȥŸȚ ȸ Ōŋ 0.1 ȸ ÀǰȭÜ ǼŸÛǪÀ ɍ ÜTS ȯȥǪÀǰÀÜ/ȬǼǰǼţä ǥÀþ ȯȥŸȚ ȸ Ōŋ 0.15 ĞǵÀìÀöä ȸ Ōŋ 10ƂÜ

.(ƂÀŎĶÀǣ) ÀȟÎȶŸö ʔÛèȥöä ĞÛȬÀöä ʔŸ3 ȯȥÔΣä ȬDZǂ VS(ȯ/ȯȥŋ 0.1) ÿȥÀǻȥÔöä ǼǼÊȭşøǼȽ

ǥǼŋ TS(ȯ/ȟ750~) ȯȥǪÀǰÀɋä ȸ Ōŋ 5 3ŋ ȟ 1.0 ʔŸ8ł ¦**Phenyl barbituric acid** ȬÀøȥǪǼäøÀǣ ȬǼÀǼÀöä Ȁþ

.ŽÀò ȯȥŸȚ ǰǪÀÀ ÜȖ3ȥDZÀöä ȷÀÀÀƨÀǣ ȬȶȟÀ ȤǰȮŋ ĬKƠ ĘəÀęǻ 3

ȯȥŸȚ ȸ Ōŋ 5 ȸ ǰÀÂŋ Ž ȟ 1.0 ǡäØł ¦**Neutral and basic impurities** ĞöǼǪȟţäş ĞǼèÀèǂä ǼəäȥÎöä

ĞȬĞÛöä ȬÊ8ł .R ĸǪǂä ȸ Ōŋ 25 3ŋ ĞȬǼęǻ 1 ǥǼŋ ȒƸş ǒÀţä ȸ Ōŋ 10ş TS(ȯ/ȟ80~) ÿȥÀǻȥÔöä ǼǼÊȭşøǼȽ

ÜĞ3Àè 1 ǥǼŋ °ÿ105 ǥøäÀǵ ĞDZøǻ Ž ĞöÀȶǰöä ȤÀΘş ÛĸǪǂä ÀǺĞÀ ÛöÀţä ȸ Ōŋ 5 ȯÀȶȟǪèÀǣ ǥÀŋ Ȭȭ Ûğ äÀŋ 3 ĞÀĸǪǂä

.ŊŸŋ 3.0 ȸ ÀǰȭÜ ĞöÀȶǰöä ȷÂǩ ɍ

ĞȬǼęÀöä ĞȬĞÛöä ǡäÀÎǪèä" ȷäȥÀ3 ĬKƠ 8ȥòȥŋ ȥȽ Àȶȭ øÀĞǪǹɍä ĘĞÛł ¦**Related substances** ĞöÀÎţä ǻäȥţä

80 ȸ ǰÀÂŋş ĞǼŸ8ŋ ǥÀȶȭ R2 ÀȮǼŸǼÊöä ĞŋɎȽ ȯÀȶȟǪèÀǣ Û(84 ĞȞÀÔöä Û1 ǼŸȬä) "Thin-layer chromatography

260~) ÀǼǪȥŋǂä ȯȥŸȚ ȸ ÀǼǵäş ÀȶDzǵş ÛTS(ȯ/ȟ 750~) ȯȥǪÀǰÀɋä ȸ ÀȶDzǵ 15 ÛR ÿøȥȥøȥŸȮöä ȸ ÀȶDzǵ

ÛTS(ȯ/ȟ 750~) ȯȥǪÀǰÀɋä Ž ƙÀǪä ƙȯȥŸȚ ȸ ÀǪşÀȮŋ 10 ĞȞǼÀÔöä ʔŸ3 ÀŸÔÀÀŋ ĘĞÛÀ .ȭÀȞǪŋ øȥÛȭ TS(ȯ/ȟ

1 Ȭȭ Ž øÀĞǪǹɍä ǥÀŋ ȸ ŊŸŋ 0.20 ɃȥǪ3 :(B) ȯȥŸǂäş Ōŋ 1 Ȭȭ Ž øÀĞǪǹɍä ǥÀŋ ȸ ŊŸŋ10 ɃȥǪ3 :(A) ȯȥŸǂä

ĞȟìǂäŽ ǡäÀÎǪèɍä ÙÛƯ Ž ȪȞÀÀş ÛöäȥȚä Ž ȤDzǪö ȭÀǪǩ Ûǡäǡ ÀÎǪèɍä ǥKDzǵ ȸ ĞȞǼÀÔöä ţÂǪ ǼȟǢ .Ōŋ

ȬŸǩ ȸ ǥǼì ÀǰȭÜ ÛĞǼÊǼəÀöä ĞȟȬĞöä ǒÀǰǪèÀǣ ÛA ȯȥŸǂä ȸ ǰǪÀǩ ĞȟȬǢ ĞÀÜ ȷȥȮǩ ɍ .(ÀǪŋȥǪÀǪ 254) ĞǼDzÊÀÀĞöä ȧȥȥ

.B ȯȥŸǂä ȸ ǰǪÀǩ ȖøǪöä

ǥÀÛę 2 8ÅȒł ÛR ǼǼŋÀŋøȥȥ ȬǼǰǼŋ ȖəÀÀǪ ȸ Ōŋ 30 Ž ÛĞǼùȥĞȒŋ ĞǪşàȥŋ Ûȟ 0.20 ĞäàÀę ǡäØÀ ¦**Assay** ĞÊÀÀȬţä

ݍøǪǵ VS(ǿ/ǿζ ŋ 0.1) ÿζ۸ǻζÔöä ÆĿÊõζǯĿŋ ǿζŸĦŋ ÀÅĦŞ TS ÆĿŋÅŋøζζ ŌĿǯĿŋ ŪəÅǪ/ƘÅöǯζ ǿζȾĿǯöä ǿζŸƮ ȸŋ Û"Non-aqueous titration ŪəÅŋŸöä Ùèζöä Ž ģÀÅĦţä" ȷäζȝ ǨƠ ȣζòζŋ ζȽ ÅȾõ Ûåøàǂä ȷζŸöä ǧäæ ǦÅƵÅöä ǦÛŌþ ŊŸŋ 23.22 ǜζÅÓ VS(ǿ/ǿζ ŋ 0.1) ÿζ۸ǻζÔöä ÆĿÊõζǯĿŋ ǿζŸƮ ȸŋ Ōŋ 1 Ōõ .(142 ǦĦÅÔöä Û1 ÆŸÕä) ʙ ǦŌÅÙÛöä .$C_{12}H_{12}N_2O_3$ ȸŋ

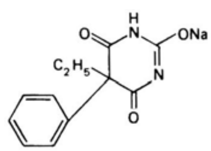
PHENOBARBITALUM NATRICUM

Phenobarbital Sodium !ǋǐǫǋȚǁ ǚƑǏǴƥǴǋǳǐȥ

$C_{12}H_{11}N_2NaO_3$ ¦**Molecular formula** ǦƁÅÅÂƨä Ǧ8ĿÔöä

254.2 ¦**Relative molecular mass** ǦĿǦÊÅöä ǦƁÅÅÂƨä ǦŸǪÓöä

¦**Graphic formula** ǦħþÅĿǦƫä Ǧ8ĿÔöä



¦**Chemical name** ŪəÅĿȾĿÓöä ȴèɼä

Sodium 5-ethyl-5-phenylbarbiturate; 5-ethyl-5-phenyl-2,4,6-(1*H*,3*H*,5*H*)-pyrimidinetrione monosodium salt; CAS Reg. No. 57-30-7.

.ǦĦəäÅöä ǅÆȝ ÜȐĿǚ Ƀøζŷæ åζĦÊŋ ȿǚ ÛöÅȐĿæ ǦÅøζŸæ (ǧäǨǯǧ) ǧÅǦĿǧ ¦**Description** Ȥòȥöä

R Ƙǫǂä Ž ÅĿŸȾȝ äåȿæ Ƙȡ ÜTS (ǿ/ȟ 750~) ǿζþÅǪǭä Ž äåȿæ ÜöÅţä Ž ȷÅæȿǾöä Àǧ ¦**Solubility** ǦĿþÅæȿǾöä

.R ÿøζζȿøζŸÓöä Ž ɼȿ

.ȝŶǪǹä ǻÅȐŋ ÜÙÆƵħ ÜÿǭÅħ ¦**Category** ǦÅǺöä

.öζȐöä ȸŋ ǦĿȾƮ ÛÿÅÓǵǚä ǦŌŸ8ŋ ǦÅȿÅǵ Ž ÿζ۸ǻζÔöä ǿÅǪĿæøÅæζĿζ ȘÅǵ Æȥ ¦**Storage** ȸÅÂǺǪöä

äÅĿȡ Ž ݍøǪǵ .ǦǦùÀǪÊŋ ǥǻÅŋ ÿζ۸ǻζÔöä ǿÅǪĿæøÅæζĿζ ǂĚĿ ¦**Additional information** ǦĿζÅȓÜ ǧÅŋζŸĦŋ Ž ţÀèÜ ŌÓÅǪöä ȷζÓÅȿ ÛɃζƨä ƿÅţä Ǧæζùǚö ôÀĦǪöä ÆȝȝÅ ǰÅøÆǪÅæ ōøÆǪÅ ÿζ۸ǻζÔöä ǿÅǪĿæøÅæζĿζ ȷǚζ öζȐöä .ݍŸȝǂä ǥøäÀΣä ǧÅǄøǻ

REQUIREMENTS ƘǦǘǐƱƙǳ!ƒ

General requirement … $C_{12}H_{11}N_2NaO_3$ … %98.0 … %101.0 …

Identity tests:

- … A … B … C … D …

A: … "Spectrophotomotry in the infrared region … (43 …) … *reference spectrum* …

B: … 0.2 … 10 … 2 … (~70 …) TS … 105° … 175° … C …

C: … 20 … B … 5 … (~750 …) TS … Cobaltous chloride TS … (~100 …) TS …

D: … General … "identification tests … (123 …) … 20 …

Clarity and Colour of solution: … 1.0 … 10 … R … 15 …

Loss on drying: … 140° … 70 …

pH value: … 0.10 … R … 9.0 – 10.8.

Neutral and basic impurities … 1.0 … 5 … (~80 …) TS … 10 … 25 … R … 1 … 105° … 5 … 3 … 3.0 …

ǦŐĿƹÀöä ǦŐǤÛöä ăäÀÎộèä" ɹäζÂȝ ǨƠ 8ζòζɳ ζȽ Àŧõ øÀǦộǹɍä ĘǤÛŀ :**Related substances** ǦŏÀÎţä ắäζţä 80 ȡɳ ǰÂɳş ǦŸǰ8ɳ ǥắÀŧõ R2 ÀÒĿŸĿÊöä ǦɳƳȽ òÀŧǶộèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸÕä) "Thin layer Chromatography 260~) ÂĿõÀộæ ÀĿộζɳɉä òζŸȚ ȡɳ ȳζǅǵ 5ş TS (ò/ȟ750~) òζộÀǯÂɋä ȡɳ ÀŧǅǵΊ 15 ÛR ȳøζζşøζŸÒöä ȡɳ ÀŧǅǵΊ ÛTS (ò/ȟ 750~) òζộÀǯÂɋä Ž ƙòζŸɉä ȡɳ Őõ ȡɳ Àộöş ÀÒɳ 10 ǦĦĿÀÔöä ɁŸȝ ŸÔÀÂɳ ĘǤÛŀ .õÀĦộɳ øζÛõ (ò/ȟ Őõ Ž øÀǦộǹɍä ǥắÀɳ ȡɳ ŊŸɳ 0.20 ɃζƷ :(B) òζŸɉäş Őɳ 1 Őõ Ž øÀǦộǹɍä ǥắÀɳ ȡɳ ŊŸɳ 10 ɃζƷ :(A) òζŸɉä ȧζζ ǦĤìɉä Ž ăäÀÎộèɍä ÙÛƯ ÒĦÀÂş ÛöäζŢä Ž ȤǅǵộöõÀộǩ Ûăä ÀÎộèɍä ǥƘǅǵ ȡɳ ǦĦĿÀÔöä ţÂộ ÆĤæ .Őɳ 1 ɄøộöäŐŸǩ ȡɳ ǥÆì ÀǯõÛ ÛǦĿÊĿəÀöä ǦĤŐǤöä öÀǯộèÀæ ÛA òζŸɉä ȡɳ ǰộÀǩ ǦĤŐæ ǦÀÛ ɹζÒǩ ɼ .(ÀộɳζộÀộ 254) ǦĿǅÊÀǤöä .B òζŸɉä ȡɳ ǰộÀǩ

ȐƥòζŸȚ ȡɳ Őɳ 5 8ÀȒÂ ÛöÀţæ ȡɳ Őɳ 15 Ž ÛǦĿùζǤȒɳ ǦộşàζɳÛȟ 0.5 ǦäÀę ăäØŀ :**Assay** ǦÊÂÀŐţä 25 ǥÀɳ Őõ Ž ÛǦǦęÀĦộɳ ğÀĿŧÒæ ŐöæÆĤæş R ƘộɉäȡɳŐɳ 50 øæ ÒŸÁộÊÂş ÛVS (ò/òζɳ 2) ŐÂøζŸõşøÆĿŢä .ǥÀɳ Őõ Ž Őɳ 5 òÀŧǶộèÀæ ÛöÀţÀæ ƙǩÀɳ ǦǤõÀţä ğÀòƳƪäŐÊ8ŀ .ŸɳÀõ îƳÁộèɍä ĘŐĦộÂ ɁøộǵÛƘộɉä ȡɳ Őɳ ȡɳ Őɳ 2 8ÀȒÂ ÛȐÀÁÀɳ ȽǅǵБÛ òζòζöä ɁøộǵÀÁǤǩÛǦĿÊĿəÀöä ƘộɉäǦòƳǹБÛƘộɉäǦòƳǹ8ÀȒÂ Őõ .°ȳ105 ǥøäÀǵǦǅøắŽ ǨäÀǯöä ɹàζöä ɁøộǵǦöÀŧǯöä ȤÀƟş Û8ÀÂƨä ɁøộǵÀÁǤÂÛR öÀţä ţşÂøÀɳ òζộÀǯÂɋä .$C_{12}H_{11}N_2NaO_3$ ȡɳ ȟ 1.095 ùζÀÒÂ ǦöÀŧǯöä ȡɳ ȟ 1

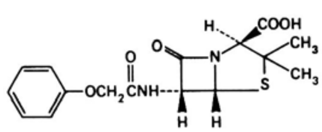
PHENOXYMETHYLPENCILLINUM

Phenoxymethylpencillin ǅǷɉƨǳǤĺĺǫ üǏƙǏǅ Ǐƨ ĺǋǳǏƺ

$C_{16}H_{18}N_2O_5S$:**Molecular formula** ǦǺÀÂƨä Ǧ8ĿÔöä

350.4 :**Relative molecular mass** ǦĿǤÊÀöä ǦǺÀÂƨä ǦŸộÒöä

:**Graphic formula** ǦǶộÀĿǤţä Ǧ8ĿÔöä



:**Chemical name** ɄəÀĿŧĿÒöä Ƚèɍä

(2*S*,5*R*,6*R*)-3,3-Dimethyl-7-oxo-6-(2-phenoxyacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6[(phenoxyacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid: CAS Reg. No. 87-08-1.

[illegible] **Description** [illegible].

[illegible] **Solubility** [illegible] 1700 [illegible] 7 [illegible] (~750 [illegible]) TS.

[illegible] **Category** [illegible].

[illegible] **Storage** [illegible].

[illegible] **Additional information** [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] %95.0 [illegible] %102.0 [illegible] $C_{16}H_{18}N_2O_2S$ [illegible].

Identity tests [illegible]:

- [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 2 [illegible] 1 [illegible] (~1760 [illegible]) TS [illegible].

C: [illegible] 2 [illegible] 1 [illegible] TS [illegible].

Specific optical rotation [illegible] 10 [illegible] -1 [illegible] R [illegible] $[\alpha]_D^{20°C}$ = +186 to 200° [illegible].

Determination of water by ÀÎĒ ȯøÅÕ ǦÕÀÛ ŏÅţ ƙĒĦ" ȷǟƺ ǨƠ ȣǭȯǭ ǭĿ Åŧ ȡĦ ¦**Water** ŏÅţ ȡʒ ǼÂÂ ɍ ÜǵÅţ ȡ ȟ 0.3 ƂǟǵǴ ȯÅŧȞèÅ Û(145 ǦĦÀÔ Û1 ǼŸÕ) B ǦÕÀÛ Û"the Karl Fischer method .ȟ/ȠŸ 15

.4 – 2.4 ÛŏÅţ Ž Ōȡ/ȠŸ 5.0 ÂĒÕÀ ĘŸȞÊȠ ŏÅŁÅ ȠŸ ¦**pH value** ŏÅŁÅ ǦŧĒ

Ûȟ 0.1 ǦǟÀę ā ǟǾł ¦***p*-Hydroxyphenoxymethyl penicillin** ƙŸÊÅ ŌĒȠ ɄÊÕǭĒ ɄÊÕşøǼĒŁ - ǟøÅ .Ōȡ 100 ȴDzƜ ȯǭŸŢ ŏÅÛʒȹ VS (ȯ/ȯǭ 0.1) ȳǭÅǵǭÔ ǼĒÊÕşøǼĒŁ ȯǭŸŢ ȡ ǦĒǭÅÕ ǦĒŧÕ Ž ÛǦĒùǭȒȠ Ǧşàǭ ǧǟǨDzǵ ȯÅŧȞèǟ ŌȒÅł) 0.36 ȡʒ ǼÂÂ ɍ ÜÀȠǭÅ 306 ǦǟÀę ǦDzǭ ȯǭù Ž ȴè 1 ǦÅǺǟ ǦÕÛ î Åŧǟ âÅÕÅ .(ȴè 1 ǦÅǺǟ ǦÕÛ î Åŧǟ ǼÊƷş âÅĒÕ ȴè 2 ÈĒÕ

ȡ ǰǨÅ ȯǭŸǂǟ ȡ Ōȡ 20 ȤÅǺł ¦**Ultraviolet absorbance range** ǦĒDzÊÀǟ ȧǭ ǦĦȉȷǟ î ÅȹȯÅƒ ÂĒÕÀ ȳǭÅǵǭÔ ǼĒÊÕşøǼĒŁ ȯǭŸĦȠ Ōȡ100 ƂÜ ƙŸÊÅ ŌĒȠ ɄÊÕǭĒ ɄÊÕşøǼĒŁ -ǟøÅ øǟ î ÅȵǟøÅȹȵɍǟ ȡʒ î Åŧǟ ŌÕÅ ɍ Ü ÀȠǭÅ 274 ǦǟÀę ɄŧȚʒÜ ǦDzǭ ȯǭù Ž ȴè 1 ǦÅǺǟ ǦÕÛ î Åŧǟ âÅÕÅ .VS (ȯ/ȯǭ 0.1) .0.62 ȡʒ ǼÂÂ ɍş 0.56

ƙDzşøǼĒŁ ǧÅǭÀÕ ȯǭŸŢ ȡ Ōȡ 0.6 ȡ ǰÂȠ Ž ÛǦĒùǭȒȠ Ǧşàǭ ÛȠŸ 50 ǦǟÀę ā ǟǾł ¦**Assay** ǦÊÀÕţ ŌÕł .Ōȡ 1000 ȴDzǵ ƂÜ ȯǭȯǭ ʔøȹǵ ŏÅţ ȡ ǦĒǭÅÕ ǦĒŧȮ ȤÅǺłş ŏÅţ ȡ Ōȡ 10ş TS (ȯ/ȟ 40) ȳǭÅǵǭÔ ȯşȷǟ āǭȷǟ ƂÜ ȣÅȒł .ǵǟǼÊǟ ǻşÂȠ ÅŧȚȠ ŌÕ ƙŸÔÅȠ ƙǟǭÜ ƂÜ ȯǭŸǂǟ ǟǾŁ ȡ Ōȡ 2 ÅŧȚȠ ŌÕ ȷÅȠÅÊę ǵǼȠ °ȳ60 ǵøǟÀǵ ǦDzøǻ Ž ɄǟȠ ȳÅƥ Ž ʒȓǭş Ûāǭȷǟ ǼÊł ÛTS ĘǦÂǟ ǼøǭŸÕ/ȯşǟǼĒƺÜ ȯǭŸŢ ȡ Ōȡ 10.0 Ōȡ 10.0 ɄøǺǟ āǭȷǟ ƂÜ ȣÅȒ .(A ȯǭŸǂǟ) °ȳ20 ǵøǟÀǵ ǦDzøǻ ƂÜ ǦʒÀÊǟ āǭȷǟ ǻĦł .ÙǦȒÅǟ ǦÕęǻ 25 .(B ȯǭŸǂǟ) ǯÂƺş ŏÅţ ȡ

ʔŸʒ ɃǭȹƠ ǼÂǾȠ ǦĒŸȵ ŌǟÅÕȠ ÀȠǭÅ 325 ɄŧȚʒÜ ǦDzǭ ȯǭù Ž ȴè 1 ǦÅǺǟ ǦÕÛ î Åŧǟ ƘȵǨ ȷşǻ âÅÕł .B ȯǭŸǂǟ ŌDzȷ ŏÅȠş A ȯǭŸǂǟ ŌDzȷ TS ĘǦÂǟ ǼøǭŸÕ/ȯşǟǼĒƺÜ ȯǭŸŢ ȡ Ōȡ 10.0ş ŏÅţ ȡ Ōȡ 2.0 ȡ ǰÂȠ ʒȠ ǦøÅÕţÅ ǦȯǭĦÀţ ǵÅţ Ž $C_{16}H_{18}N_2O_5S$ ǦĒŧÕ ǼÊƠ ÛB ȯǭŸǂş A ȯǭŸĦŧŸ î Åŧǟ ƙǟ ȧÀÅǟ ȡ ƙDzşøǼĒŁ ǧÅǭÀÕ ȯǭŸŢ ǦǭÅȓÜ ȣǾƜ ȡȮ ÛȡǟÀǟş ǦŏÅÎţÅ ǦȯǭĦÀţ R ƙŸÊÅ ŌĒȠ ɄÊÕǭĒ ȳǭĒèÅǭ 0.902 ùǭÅȮÅ ($C_{16}H_{17}KN_2O_5S$) RS ƙŸÊÅ ŌĒȠ ɄÊÕǭĒ ȳǭĒèÅǭ ȡ ȠŸ 1 ŌÕ ÜTS (ȯ/ȟ40) ȳǭÅǵǭÔ ȤĒÛ âÅĒÕȠ Ž ɄȞDzÀţ ȯǭŸĦŧŸ î Åŧǟ ȷǭȮÅ ȷÜ Ǽƶ .($C_{16}H_{18}N_2O_5S$) ƙŸÊÅ ŌĒȠ ɄÊÕǭĒ ȡ ȠŸ .0.03 ± 0.63 ǦÂÀȮ ÀĦţ ɄǝǭȒ

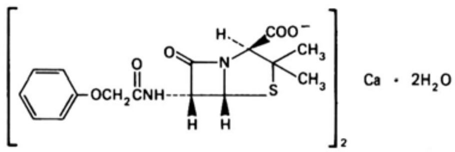
PHENOXYMETHYLPENICILLINUM CALCICUM

Phenoxymethylpenicillin calcium Ǌĭǂƨ ǌĨǁĩ üĭƙĭĎǅ Ĭ ƨ ǀ Ǌǌĭǅ !Ǌĭƨ ǁƑ ǀ

$C_{32}H_{34}CaN_4O_{10}S_2,2H_2O$ ș $(C_{16}H_{17}N_2O_5S)_2Ca,2H_2O$ ¦**Molecular formula** ǦǼǻÂƨă Ǧ8ǼÔöă

774.9 ¦**Relative molecular mass** ǦǼÊǺöă ǦǼǻÂƨă ǦŸǪȮöă

¦**Graphic formula** ǦǾǼǦţă Ǧ8ǼÔöă



¦**Chemical name** ȽəǼȶǼȮöă ǈèƒă

Calcium bis[(2*S*.5*R*.6*R*)-3,3-dimethyl-7-oxo-6-(2-phenoxyacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate] dihydrate; calcium bis[[2*S*-(2*α*,5*α*,6*β*)]3,3-dimethyl-7-oxo-6-[(phenoxyacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate] dihydrate; CAS Reg. No. 73368-74-8.

.ǦǺǼǶ ȑ ǵÂǼư ǦȞəăȀǣ ș ǦȞəăȀöă ǅǼȝ ÜȒǼǣ ÛǈǫǺ ȹøǶŸǣ ȧǶȞÊȠ ¦**Description** Ƶòȥöă

.ǒǺţă ȸȠ ǻõÂǅ 120 Ž ǒȖǢ ă șǾǺ ¦**Solubility** ǦǼǾǺșǾöă

.ȹǶǼǵ ǻǺȒȠ ¦**Category** ǦǺǺöă

.ǻǼǼǅ ǦȎŸ8ȠǦǺșǺǵ Ž ƙŸÊǼöă ȮǼǮȠ ȽÊȭǶǼǶ ȳǶǼÊȮǺȭ ȘǺǵ Ǽȥ ¦**Storage** ȸǺÂǺǪöă

ȭøǼǪǺ ƙŸÊǼöă ȮǼǮȠ ȽÊȭǶǼǶ ȷǶǶ ÛǒǶȒöă ăǺǼȡ Ž ʔøǪǵ ¦**Additional information** ǦǼǶǺȑ ǵǺȠǶŸȠ

.ʔŸȝȷă ǵøǺÀΣă ǵǺǅøǻ Ž ţǺèÜ ȪȮǺǪöă ȷǶȮǺș ÛȹǶƨă ƿǺţă ǦǻǶüǺö ôǺȞǪöă ǼǺȝ ȷǺøǼǪöǻ

REQUIREMENTS ƘǦǵǭƱǩǆ!ƒ

ǼǺÂǺ ƒș %95.0 ȸȝ ȮȭǺ ƒ ǺȠ ʔŸȝ ƙŸÊǼöă ȮǼǮȠ ȽÊȭǶǼǶ ȹǶǪȜ ¦**General requirement** ȳǺǶöă ǼŸÛǪţă

.ǦǼǺȠŸöă ǵǺţă ȻÜ ţǶǅǺöǺ ǦǻǶÊȚ Û$(C_{16}H_{17}N_2O_5S)_2Ca$ ȸȠ %102.0 ȸȝ

:**Identity tests** ǶǏǊǇǈǁǆ ǀ ǲǷǦǴǭǁ

.D ș C ș B ǵăøǺǪȒƒă ș D ș A ȸǺøǺǪȒƒă ǺȠÛ ȨǼÛǺ ȸȮǵ •

ǒǺǺȶΣă ǨǑ ǦǶȑ ȷă ǦȭÛǺȠ Ž ȽəǶȒöă ƵǼÛöă ăǺǼș" ȷǶǶȝ ǨǑ 8ǶòǶȠ ǶȽ ǺȶȭȮ ȮǶǺöă ȨǦÛǺ :A

ǨǑ ǦǶȑ ȷă Ž î ǺÔǪȠƒă ƵǼù ȨǼǺÛǪǺ .(43 ǦǶǺÔöă Û1 ǼŸȮă) "Spectrophotometry in the infrared region

reference spectrum ȽǶǅǺţă *ƵǼÛöă* ȝȠ ș RS ƙŸÊǼöă ȮǼǮȠ ȽÊȭǶǼǶ ȳǶǼÊȮǺȭ ȸȠ ȷǺǺöă ƵǼÛöă ȝȠ ǒǺǺȶΣă

[illegible].

B: [illegible] 2 [illegible] 2 [illegible]
[illegible] TS (~1760) [illegible]
[illegible].

C: [illegible] 2 [illegible] 2 [illegible]
[illegible] TS [illegible]
[illegible] –

D: [illegible] (~70) [illegible] TS [illegible]
[illegible] (~100) [illegible] TS [illegible]
"General identification tests [illegible] (120 [illegible] 1 [illegible]).

Water [illegible] "Determination of water by the Karl Fischer [illegible] A (145 [illegible] 1 [illegible]) 0.2 [illegible] 50 [illegible].

pH value [illegible] 5.0 [illegible] R [illegible]
5.0– 7.5.

p-Hydroxyphenoxymethylpenicillin - [illegible] 0.11 [illegible]
[illegible] (0.1 [illegible]) VS [illegible]
100 [illegible] 1 [illegible] 306 [illegible] 0.36 [illegible]
([illegible] 2 [illegible] 1 [illegible]).

Ultraviolet absorbance range [illegible] 20 [illegible]
VS (0.1 [illegible]) [illegible] –
[illegible] 100 [illegible] 1 [illegible] 274 [illegible]
0.56 [illegible] 0.62 [illegible].

Assay [illegible] 50 [illegible]
1000 [illegible] 2.0 [illegible]
10.0 [illegible] TS [illegible]
60 [illegible] 25 [illegible] 20° [illegible] (A [illegible])
(B [illegible]) 10.0 [illegible].

325 ... 1 ...

B ... A ... TS ... 10.0 ... 2.0 ...

$(C_{16}H_{17}N_2O_5S)_2Ca$ ... B ... A ...

1 ... RS ...

0.951 ... $(C_{16}H_{17}KN_2O_5S)$ RS ...

0.03 ± 0.63 ... $(C_{16}H_{17}N_2O_5S)_2Ca$.

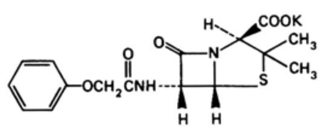
PHENOXYMETHYLPENICILLINUM KALICUM

Phenoxymethylpenicillin potassium

$C_{16}H_{17}KN_2O_5S$:**Molecular formula**

388.5 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

Potassium (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenoxy-acetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate; potassium [2*S*-(2*α*,5*α*,6*β*)]-3,3-dimethyl-7-oxo-6-[(phenoxyacetyl)amino]-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylate; CAS Reg. No. 132-98-9.

:**Description**

R ... 1.5 ... :**Solubility**

:**Category**

:**Storage**

:**Additional information**

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] %95.0 [illegible] %102.0 [illegible] $C_{16}H_{17}KN_2O_5S$ [illegible].

Identity tests [illegible]

- [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotmetry in the infrared region" [illegible] (43 [illegible]) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 2 [illegible] 2 [illegible] (~1760 [illegible]) TS [illegible].

C: [illegible] 2 [illegible] 2 [illegible] TS [illegible].

D: [illegible] 2 [illegible] (~80 [illegible]) TS [illegible] "General identification tests" [illegible] (123 [illegible]).

Specific optical rotation [illegible] 10 [illegible] $[\alpha]_D^{20°C}$ 215 to 235° [illegible].

Clarity of solution [illegible] 0.2 [illegible] 10 [illegible].

Loss on drying [illegible] 105° [illegible] 15 [illegible].

pH value [illegible] 5.0 [illegible] R [illegible] 5.0 – 7.5.

***p*-Hydroxyphenoxymethylpencillin** [illegible] 0.11 [illegible] (0.1 [illegible]) VS [illegible]

ǑȒǺǺ) 0.36 ȸȝ ǼǺÂǺ ɍ ǛǞǪȠȤǬǺǬ 306 ǦǽǻǞȩ ɄȾȚȝǕ ǦDzȤȠ ȯȤù Ž ȴè 1 ǦǬǺǺǰǽ ǦǑǦǕǑ ȋ ǺȾǪǑǻ ǡǺǑǺ .Ǒȵ100

.(ȴè 1 ǦǬǺǺǰǽ ǦǑǦǕǑ ȋ ǺȾǪǑǻ ǼÊȜȿ ǡǺǼǑǛǑ ȴè 2 ÈǼǑǩ ğǻKDzǵ ȯǺȾǶǪèǻ

ȸȵ ǰǩǺǺǑǻ ȯȤǛǂǻ ȸȵ Ǒȵ 20 ȤǺǺȽ ¦**Ultraviolet absorbance range** ǦǼDzÊǺǺǦǑǻ ȧȤȤ ǦǶȉǂǻ ȋ ǺǬ ȯǺƒ

ʔǛȝ ȯȤÔǶǛǑ VS (ȯ/ȯȤȵ 0.1) ȳȤǺǻȤÔǑǻ ǼǼÊǑȿøǼǼȽ ȯȤǛǶȵ ƘǛÊǺǦǑǻ ǑǼǰǼȵ ɄÊǑȤǼȤ ɄÊǑȿøǼǼȽ -ǻøǺǽ øǺǦǪǹǻ

ɍȿ 0.56 ȸȝ ǑǑǺ ɍ ǛǞǪȠȤǬǺǬ 274 ɄȾȚȝǕ ǦDzȤȠ ȯȤù Ž ȴè1 ǦǬǺǺǰǽ ǦǑǦǕǑ ȋ ǺȾǪǑǻ ǡǺǑǺ .Ǒȵ 100 ȴDzǁ ȯȤǛȚ

.0.62 ȸȝ ǼǺÂǺ

.Ǒȵ 1000 ȴDzǵ ʔǛȝ ȯȤÔǶǛǑ ǒǺȶǻ ȸȵ ǦǼȤǺǑ ǦǼȾǑ Ž ǕǦǼùȤǦȒȵ ǦǬȿǻȤȵ ǕȠǛȵ 50 ǦǽǻǞȩ ǡǻØǺ ¦**Assay** ǦÊǺǺǑȶǻ

ǡȤǦǬǂǻ ƂǕ ȣǺȒȽ .ǵǻǻǼÊǽ ǻȿǺȵ ǺȾǺȵ ǑǑ ƘǛÔǺǺȵ ƘǽȤǦǬǕ ƂǕ ȯȤǛǂǻ ǻØȽ ȸȵ Ǒȵ 2 øǻǼǑȵ ȷǺǪȵǺÊǪ ǑǑǺȽ

ǵøǻǺǵ ǦDzøǻ Ž ɄǝǺȵ ȳǺƥ Ž ȝȑȤǺȿ Ǖ ǡȤǦǬǂǻ ǼÊȽ ǕȝÂȽȽ ǕTS ȨǦǝÂǑǻ ǼǺøȤǛǑ /ȯȿǻǻǼǼȤǕ ȯȤǛȚ ȸȵ Ǒȵ 100 ȯȿǂǻ

ɄøǬǺǰǑǻ ǡȤǦǬǂǻ ƂǕ ȣǺȒǺ .(A ȯȤǛǂǻ) °ȳ20 ǦDzøǼǑǻ ʔøǪǵ ǦȝÂÊǽ ǡȤǦǬǂǻ ǻƎȽ .ǕǦȒǑǺǽ ǦǑǼȩǻ 25 ǵǼȵ °ȳ60

.(B ȯȤǛǂǻ) ȜÂȤȿ ǒǺȶǻ ȸȵ Ǒȵ 10.0

ɃȤǪƠ ǼǺØȵ ǵKDzǵ ǑǽǺǑȵ ǞǪȠȤǬǺǬ 325 ɄȾȚȝǕ ǦDzȤȠ ȯȤù Ž ȴè1 ǦǬǺǺǰǽ ǦǑǦǕǑ ȋ ǺȾǪǑǻ ƘȖǘǩ ȷȿǻ ǡǺǑȽ

ǑDzǂ ǒǺȵȿ A ȯȤǛǂǻ ǑDzǂ TS ȨǦǝÂǑǻ ǼǺøȤǛǑ/ȯȿǻǻǼǼȤǕ ȯȤǛȚ ȸȵ Ǒȵ 10.0ȿ ǒǺȶǻ ȸȵ Ǒȵ 2.0 ȸȵ ǰǺÂȵ ʔǛȝ

.B ȯȤǛǂǻ

ǺȽøǺǦǪǹǻ ȴǪǺ ɄøǪǑǻ ǵǻǺȶǻ Ž $C_{16}H_{17}KN_2O_5S$ ǦǼȾǑ ǼÊƠ ǕB ȯȤǛǂǻȿ A ȯȤǛǶȾǛǑ ȋ ǺȾǪǑǻ Ƙǽ ȧǺǺǑǻ ȸȵ

ȯȤǛǂǻ ȋ ǺǬ ȷȤǑǺ ȷǕ Ǽƶ .ȸȵǻǺǪǑǻȿ ǦǒǺȊȶǺǽ ǦȍȤǶǺȶǻ ǕRS ƘǛÊǺǦǑǻ ǑǼǰǼȵ ɄÊǑȤǼȤ ȳȤǼèǺǩȤǽ ȝȵ ǦǬøǺǑȶǺǽ

.0.03 ± 0.63 ǦǺǺǺǑǽ ǺǼǶȵ ɄǝȤȑ ȤǼù ǡǺǼǑȵ Ž ɄǶDzǺȶǻ

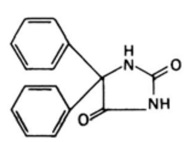
PHENYTOINUM

Phenytoin DzǏNjȞǐǼǁǁ

$C_{15}H_{12}N_2O_2$ ¦**Molecular formula** ǦǼǺǺÂƨǻ ǦȣǼÔǑǻ

252.3 ¦**Relative molecular mass** ǦǼǦÊǺǑǻ ǦǼǺǺÂƨǻ ǦǛǪǑǑǻ

¦**Graphic formula** ǦǼǬǼǦȼǻ ǦȣǼÔǑǻ



:**Chemical name** [illegible]

5,5-Diphenylhydantoin; 5,5-diphenyl-2,4-imidazolidine-dione; CAS Reg. No. 57-41-0.

[illegible] :**Description** [illegible]

[illegible] (750~) [illegible] :**Solubility** [illegible]
.R [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %101.0 [illegible] %98.0 [illegible] :**General requirement** [illegible]
$C_{15}H_{12}N_2O_2$ [illegible]

:**Identity tests** [illegible]

• [illegible] A [illegible] D [illegible] C [illegible] B [illegible].

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] *reference spectrum* [illegible] RS [illegible].

B: [illegible] 20 [illegible] 2 [illegible] (100~) TS [illegible] 5 [illegible]
(40) TS [illegible].

C: [illegible] 5 [illegible] 1 [illegible] (750~) TS [illegible] 2 [illegible]
[illegible] (80) TS [illegible] (II) [illegible] R [illegible] – [illegible].

D: [illegible] 295°[illegible].

:**Heavy metals** [illegible] 1.0 [illegible] "limit test for heavy metals" [illegible] 3 [illegible] (127 [illegible] 1 [illegible]) [illegible] A [illegible] (128 [illegible] 1 [illegible]) [illegible] 10 [illegible].

:**Sulfated ash** [illegible] 1.0 [illegible].

ȸȘ ȀǯǃȈ ǼǄȀȂ ǫ Ȉ°ȳ105 ǵǿǻȀǵ ǦǱǽǿǻ Ž ǨǽȀǯǃǻ ȷȁǽǃǻ ȝøǪǵ ǽȀǱǽǲ ¦**Loss on drying** ǽǼȀǱǽǪǃȀǽ ǼǄȀǃǻ
.ȟ/ȘȳȘ10

ȗǝȀȀǾ ȸȘ ƃȀƪǻ ǒȀȶǻ ȸȘ ǑȘ 40 ȝȘ ǵǼǵǻȘ ǦǄǼȘǻ ǵǼȘ ȟ 2 ȄȀǺ ¦**Acidity or alkalinity** ǦȀǽȳǄǃǻ ȘȈ ǦȑǽȶƩǻ
ɃȈ ȷǪȀȀ ǫ ȈTS ȯǽǾȀǯȀȈ/ǨȀǄȀǯǽ ȯǽǼǽ ȯǽȳƬ ȸȘ ȷȀǨȀȖȘ ǦǵȀȉȀǃǻ ȸȘ ǑȘ 10 ƃȈ ȣȀȒȀ .ǴȉȀȘ ȖR ȷǽǽȀȮǃǻ ǼǼȆǃȈ
ɄȳȀǾȀȘ ȷǽȯ ȷǪȀȀ ȈVS (ȯ/ȯǽȘ 0.01) ǧȀǾǽǽȀȮǃǻ ȸȘ ƃȀƪǻ ȳǽȀǻǽȎǃǻ ǼǼȆǃȘǿǼǼ ȯǽȳƬ ȸȘ ǑȘ 0.15 ȣȀȒȀ .ȷǽȯ
ǵȀȶǧ ȯǽȳƬ ȸȘ ǧǻȀȖȘ ȄȐȘ VS (ȯ/ȯǽȘ 0.1) ǑȀǿǽȳǃȘǿǼȚǻ Ȑƥ ȯǽȳƬ ȸȘ ǑȘ 0.3 ȣȀȒȀ .(ɃǻǿȘ Ȁƥȉ)
.ƃȀǄǨȀǽ ȘȈ Ȁƥȉ ȷǽȯ ȷǪȀȀ ȈTS ȯǽǾȀǯȀȈ/ǑǼǯǼȶǻ

ȷȀǨȀȖȘ ȣȀȒȀ ȖR ǼǼȘȀȘǿǽǽ ǑǼǯǼȘ ȗǝȀȀǾ ȸȘ ǑȘ 50 Ž ȖǦǼȕǽǴȒȘ ǦǾȘȁǽȘ Ȗȟ 0.5 ǦǽǻȀȘ ǡǻǾȀ ¦**Assay** ǦȆȀȀǑȶǻ
ȝøǪǵ VS (ȯ/ȯǽȘ 0.1) ȳǽȀǻǽȎǃǻ ǼǼȆǃǽǯǼȘ ȯǽȳȞȘ ȀȀȀȞȀȘ TS ǼǼȘȀȘǿǽǽ ǑǼǯǼȘ ȗǝȀȀǾ/ȯǽȶǼǯǃǻ ǦȘǿȁ ȯǽȳƬ ȸȘ
Ȗ"Non-aqueous titration ȗǝȀȘȳǃǻ ȕȅǽǃǻ Ž ǵȀȀȀȞȶǻ" ȷǻǽȀȝ ǨƠ ȣǽȯǽȘ ǽȽ ȀȶǑ Ȗȧǿȁǡǻ ȷǽȳǃǻ ǧǻǽ ǦȀȀȚȀǃǻ ǦȖǑǾ
ȘȳȘ 25.23 ȕǽȀȮȀ VS (ȯ/ȯǽȘ 0.1) ȳǽȀǻǽȎǃǻ ǼǼȆǃǽǯǼȘ ȯǽȳƬ ȸȘ ǑȘ 1 ǑǑ .(142 ǦȞȀȎǃǻ Ȗ1 ǼȳǑǻ) ɞ ǦǄȀȀȖǃǻ
.$C_{15}H_{12}N_2O_2$ ȸȘ

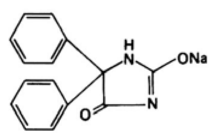
PHENYTOINUM NATRICUM

Phenytoin sodium !ǋǐǑǋȚǁǋ ǊǐǋǋǐǏǐ

$C_{15}H_{11}N_2NaO_2$ ¦**Molecular formula** ǦǼȀȀȂȥǻ ǦȣǼȎǃǻ

.274.3 ¦**Relative molecular mass** ǦǼǴȆȀǃǻ ǦǼȀȀȂȥǻ ǦȳǪȮǃǻ

¦**Graphic formula** ǦǼǾȀǼǴǵǻ ǦȣǼȎǃǻ



¦**Chemical name** ȗǝȀǼȶǼȮǃǻ ȴȅȓǻ

5,5-Diphenylhydantoin monosodium salt; 5,5-diphenyl-2,4-imidazolidinedione monosodium salt; CAS Reg. No. 630-93-3.

.ǦȞǝǻȀǃǻ ǴǼȝ ȈȐǼǽȈ ȧǽȞȆȘ ¦**Description** ǽȍǽǃǻ

[illegible] **Solubility** [illegible]
[illegible] (~750) [illegible]

Category [illegible]

Storage [illegible]

Additional information [illegible]

[illegible]

REQUIREMENTS [illegible]

General requirement [illegible] 98.5% [illegible] 101.0% [illegible] $C_{15}H_{11}N_2NaO_2$ [illegible]

Identity tests [illegible]

- [illegible] A [illegible] D [illegible] B [illegible] C [illegible] E.

A: [illegible] 0.1 [illegible] 20 [illegible] (~70) [illegible] R [illegible] Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1) [illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] 0.1 [illegible] 1 [illegible] R [illegible] 9 [illegible] 1 [illegible] (II) [illegible] TS [illegible] 10 [illegible]

C: [illegible] 10 [illegible] 1 [illegible] TS (~100) [illegible] (II) [illegible] TS [illegible]

D: [illegible] General identification tests" [illegible] (123 [illegible] 1) [illegible] B [illegible] 20 [illegible]

E: [illegible] 0.1 [illegible] 20 [illegible] (~70) [illegible] R [illegible] 295 [illegible]

[illegible] 6 [illegible] 24 [illegible] 1.0 [illegible] **Heavy metals** [illegible] 70~) [illegible] 40 [illegible] (128 [illegible] 1 [illegible]) A [illegible] "Limit test for heavy metals [illegible] 10 [illegible]

[illegible] 8.0 [illegible] 20 [illegible] **Solution in alkali** [illegible] VS [illegible] 0.1) [illegible] 2.0 [illegible] R [illegible] Yw2 [illegible] (53 [illegible] 1 [illegible]) "Colour of liquids [illegible]"

30 [illegible] 105 [illegible] **Loss on drying** [illegible]

3 [illegible] R1 [illegible] 30 [illegible] 0.55 [illegible] **Assay** [illegible] 0.1) [illegible] TS [illegible] - 1 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible] VS $C_{15}H_{11}N_2NaO_2$ [illegible] 27.43 [illegible] VS [illegible] 0.1) [illegible] 1 [illegible] (142 [illegible]

[illegible]

Additional Requirements for Phenytoin Sodium for parenteral use

(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]"

[illegible] **Bacterial endotoxins** [illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible] 1 [illegible] RS [illegible] IU [illegible] 0.3 [illegible]

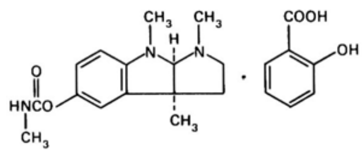
PHYSOSTIGMINI SALICYLAS

Physostigmine salicylate [illegible]

$C_{22}H_{27}N_3O_5$ [illegible] $C_{15}H_{21}N_3O_2,C_7H_6O_3$ **:Molecular formula** [illegible]

413.5 **:Relative molecular mass** [illegible]

[illegible] :**Graphic formula**



[illegible] :**Chemical name**

Physostigmine monosalicylate; (3a*S-cis*)-1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethylpyrrolo[2,3-*b*]indol-5-ol, methylcarbamate (ester), mono-(2-hydroxybenzoate); CAS Reg. No. 57-64-7.

[illegible] :**Other name** [illegible]

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] (~750 [illegible]) [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible] 1 [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] %98.0 [illegible] %101.0 [illegible] $C_{15}H_{21}N_3O_2$, $C_7H_6O_3$ [illegible]

[illegible] :**Identity tests**

A: [illegible] 10 [illegible] (~80 [illegible]) [illegible]

B: [illegible] 10 [illegible] (~100 [illegible]) [illegible] (~750 [illegible]) [illegible]

.Àþ Ęöük ÀŢŢÀ ÜöÀţÀ ȯζŸǂ ZÀȤ .ɹζŸö ǼQÎÀ ÜTS (ȯ/ȟ300~) ÂǼõÀQ ÕǼè ɉ

ÜTS (ȯ/ȟ 25) ÂǼõÀQ ÕÀǼÀǼΣ ǼÀøζŸõ ȯζŸҀ ȸɳ ǧÀÛȩ ǦĤȒ Õɳ/ɳŸɳ 10 ÂǼõÀQ ȯζŸҀ Ƃ ȣȒ :C

.TS (ȯ/ȟ750~) ȯζφÀǯÀq ǦζÀȓ ǼĤ ǼÀĿÀȿ ʔÕǦ ÛɄDzÊÀ ɹζ ÀŢŢÀ

.°ÿ186 ǦÀȩ ÛøÀŢÔφɍ ǥøÀǵ ǦDZøå :D

. $[a]_{\mathrm{D}}^{20°\mathrm{C}} = -90\mathrm{to} - 94°$ ÜÕɳ/ɳŸɳ10ÂǼõÀQ ȯζŸҀ ÕȶĤQÊÀ :**Specific optical rotation** ɄȝζÀö ɃÀÔǦ ÀȿǼQ

ǼζÀö öÀţ ȸɳ Õɳ 10 Ž ȟ 0.10 ÂǼõÀQ ȯζŸǂ ɹζȮÀ :**Clarity and colour of solution** ȯζŸǂ ɹζȿ öÀÒ

.ɹζŸö ǻǼȝȿ

.ȟ/ɳŸɳ 1.0 ȸȝ ǼÀÂÀ ɍ :**Sulfated ash** ǨÀŸÊţ åÀɳÀö

10 ȸɳ ÀǯõÜ ǼÕÀÀ ɍ Ü°ÿ105 ǥøÀǵ ǦDZøå Ž ǨÀǯö ɹàζö ʔøQǵ ZÀDzƚ :**Loss on drying** ZǼÀDzQÀ ǼÕÀö

.ȟ/ɳŸɳ

.5.2 – 4.6 ÛÕɳ/ɳŸɳ10 ÂǼõÀQ ȯζŸҀ öÀĿÀ ɳŸǦ :**pH value** öÀĿÀǦö ǦȶǼȩ

ÕÀøζŸõȿøǼŢ ȒÞ ȯζŸҀ ȸɳ ǧÀÛȩ ÈȒ Õɳ/ɳŸɳ 10 ȯζŸҀ ȸɳ Õɳ 5 Ƃ ȣȒ :**Eseridine** ȸÀǼÀÀàq

ȒÀƚ .R ÿøζζȿøζŸÒö ȸɳ Õɳ 1ȿ VS(ȯ/ȯζɳ 0.01) ÂǼõÀQ ÿζǼèÀǩζǦ ǧåζÀ ȯζŸҀ ȸɳ Õɳ 1.5 ÜTS (ȯ/ȟ70~)

.ÿøζζȿøζŸÒö ǦÕǦù Ž ɄDzÊÀ ɹζ Ƀ øζÛQÀ ɍ ÜǥǼǵȿ ǦÕǼȩå ǥǼɳ

ÿøζζȿøζŸÒö ȸɳ ǦÀȿÀÊQɳ ÿζDzǵ ǰÀÂɳ ȸɳ Õɳ 30 Ž ÛǦǼùζǦȒɳ Ǧφȿàζɳ Ûȟ0.35 ǦÀȩ āÀØƚ :**Assay** ǦÊÀÕţ

âÀǼÕɳ ǦÀÀŢÀö ƙĤƙ ÛVS (ȯ/ȯζɳ 0.1) ÕÀøζŸõǨǦö ȒȶɯǰǨÀÀö ȯζŸǂ ÀÀĤƚ .R1 ɄDzŸǯö ÕǼè ɉ ȒþȿR

Û"Non-aqueous titration ɄəÀɳŸö Ûèζö Ž ǥÀÀĤţ" ɹζÀȝ ǨƠ ȣζòζɳ ζȽ Àȶõ potentiometrically ǼŢƨ

ȸɳ ɳŸɳ 41.35 ùζÀȮÀ VS (ȯ/ȯζɳ 0.1) ÕÀøζŸõǨǦö Ȓþ ȸɳ Õɳ 1 Õõ .(142 ǦɄÀÔö Û1 ǼŸÕ) A ǦÕÀÀÛö

.$C_{15}H_{21}N_3O_2,C_7H_6O_3$

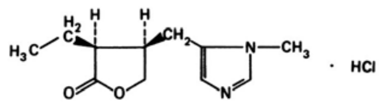
PILOCARPINI HYDROCHLORIDUM

Pilocarpine hydrochloride DžǏǦþƑǀǋǂǏǦǁǐ ǫǐþǋǂǀǋþǫǐǉ

$C_{11}H_{16}N_2O_2,HCl$:**Molecular formula** ǦƂÀÀÂƨ Ǧ8ǼÔö

244.7 :**Relative molecular mass** ǦǼǦÊÀö ǦƂÀÀÂƨ ǦŸQÒö

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Pilocarpine monohydrochloride; (3*S*-*cis*)-3-ethyldihydro-4-[(1-methyl-1*H*-imidazol-5-yl)methyl]-2(3*H*)-furanone monohydrochloride; CAS Reg. No. 54-71-7.

[illegible] :**Description** [illegible]

[illegible] (~750 [illegible]) [illegible] :**Solubility** [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] 98.5% [illegible] :**General requirement** [illegible] $C_{11}H_{16}N_2O_2,HCl$ [illegible] 101.0% [illegible]

:**Identity tests** [illegible]

A: [illegible] 10 [illegible] 5 [illegible] (~100 [illegible]) 1 [illegible] (~60 [illegible]) 1 [illegible] (100 [illegible]) [illegible]

B: [illegible] 0.05 [illegible] B [illegible] "General identification tests" [illegible] (121 [illegible] 1 [illegible])

C: [illegible] 203 [illegible]

:Specific optical rotation [illegible] 50 [illegible]

. $[\alpha]_D^{20°C}$ = + 89 to + 93° [illegible]

[illegible] 1 [illegible] 5 [illegible] 5 [illegible] 0.05 [illegible] :**Nitrates** [illegible] TS(~1760) [illegible] R [illegible] [illegible].

[illegible] 10 [illegible] 1.0 [illegible] :**Clarity and colour of solution** [illegible].

[illegible] 3.0 [illegible] :**Sulfated ash** [illegible]

20 [illegible] 105 [illegible] :**Loss on drying** [illegible].

.5.2 – 3.8 [illegible] 5.0 [illegible] :**PH value** [illegible]

[illegible] :**Related alkaloids** [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin layer chromatography [illegible] TS (~260) [illegible] 0.4 [illegible] R [illegible] 20 [illegible] R [illegible] 25 [illegible] 50 [illegible] :(A) [illegible] 5 [illegible] 1.0 [illegible] :(B) [illegible] TS2 [illegible] .B [illegible] A [illegible]

[illegible] R1 [illegible] 30 [illegible] 0.5 [illegible] :**Assay** [illegible] VS (0.1 [illegible]) [illegible] TS [illegible] 10 .(142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible] 24.47 [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] .$C_{11}H_{16}N_2O_2,HCl$

[illegible]

Additional requirement for pilocarpine hydrochloride for sterile use

Test for sterility of non-injectable [illegible] .([illegible] 32 [illegible] 5 [illegible]) *preparations"*

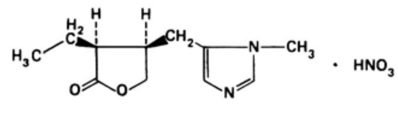
PILOCARPINI NITRAS

Pilocarpine nitrate [illegible]

$C_{11}H_{16}N_2O_2,HNO_3$: **Molecular formula** [illegible]

271.3 : **Relative molecular mass** [illegible]

: **Graphic formula** [illegible]



: **Chemical name** [illegible]

Pilocarpine mononitrate; (3*S*-*cis*)-3-ethyldihydro-4-[(1-methyl-1*H*-imidazol-5-yl)methyl]-2(3*H*)-furanone mononitrate; CAS Reg. No. 148-72-1.

[illegible] : **Description** [illegible]

[illegible] (~750 [illegible]) [illegible] : **Solubility** [illegible]
[illegible]

[illegible] : **Category** [illegible]

[illegible] : **Storage** [illegible]

[illegible] : **Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] 98.5% [illegible] : **General requirement** [illegible]
[illegible] $C_{11}H_{16}N_2O_2,HNO_3$ [illegible] 101.0%

: **Identity tests** [illegible]

[illegible] 1 [illegible] (100 [illegible]) [illegible] 5 [illegible] 10 [illegible] :A
[illegible] 1 [illegible] (60~) [illegible]

. [illegible] TS (ح/ح 100) [illegible]

(ح/ح 15) [illegible] 2 [illegible] 0.05 [illegible] 2 [illegible] :B

[illegible] "General identification tests [illegible]" [illegible] A [illegible] TS

.(122 [illegible] 1 [illegible]) [illegible]

. [illegible] °176 [illegible] :C

[illegible] 50 [illegible] **Specific optical rotation** [illegible]

. $[\alpha]_D^{20°C}$ + 80 to +83° [illegible]

[illegible] 30 TS (ح/ح 130~) [illegible] 2 [illegible] 0.7 [illegible] **Chlorides** [illegible]

"Limit test for chlorides [illegible]" [illegible]

. [illegible] 0.35 [illegible] (124 [illegible] 1 [illegible])

[illegible] 10 [illegible] 1.0 [illegible] **Clarity and colour of solution** [illegible]

. [illegible]

. [illegible] 2.0 [illegible] **Sulfated ash** [illegible]

20 [illegible] °105 [illegible] **Loss on drying** [illegible]

. [illegible]

.4.5 – 3.5 [illegible] 5.0 [illegible] **pH value** [illegible]

[illegible] **Related alkaloids** [illegible]

[illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin - layer chromatography [illegible]

(ح/ح 260~) [illegible] 0.4 [illegible] R [illegible] 20 [illegible] R [illegible] 25 [illegible]

[illegible] 50 [illegible] :(A) [illegible] 5 [illegible] TS

[illegible] 1 [illegible] 1.0 [illegible] :(B) [illegible] 1 [illegible]

[illegible] TS2 [illegible]

.B [illegible] A [illegible]

[illegible] R1 [illegible] 30 [illegible] 0.55 [illegible] **Assay** [illegible]

Non-aqueous [illegible] VS (ح/ح 0.1) [illegible]

27.13 ùʐȦȮʌ VS (ȯ/ȯʐɳ 0.1) ǬʌøʐŸǬƘǤä Ȁ þ ȸɳ Ǭɳ 1 Ǭõ .(142 ǦȞȦÔä Û1ÆŸǑä) A ǦǬʌȦÛä Û"titration
.$C_{11}H_{16}N_2O_2,HNO_3$ ȸɳ ŊŸɳ

!ǐŧƴǁɛ üƑǅƴŧƨ űǁ ɱƴǅǁɛ ǅĭǤþƑ ǈǂĭǤǁɛ ǀ ɛþǂ üɯǓ Ǐʒ ƑȚǡ ƒǂƯǂǅ

Additional requirement for pilocarpine nitrate for sterile use

Test for sterility of non-injectable ȸǬȞʋǬ ǦŸǣȦǬä Ƙɖ ğäȦȒȞʠÊʈ ǦɳȦǬʒ ǬǅƷ øȦǤɳ"ɼä" Ƃ Ǣ ÆǂǅʐÊʌ
.(ǦȦÆŸƱɋ ǦȞǤÛä Ž 32 ǦȞȦÔä Û5 ÆŸǑä ȦȚɸä) *preparations"*

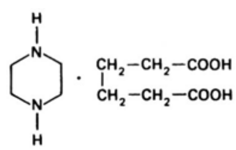
PIPERAZINI ADIPAS

Piperazine adipate ǅĭȒɛþĭǤĭǤǁɛ ǀƑǤĭɱƈ

$C_{10}H_{20}N_2O_4$ ȿǕ $C_4H_{10}N_2,C_6H_{10}O_4$ ¦**Molecular formula** ǦȻȦʌÂƨä Ǧ8ƐÔä

232.3 ¦**Relative molecular mass** ǦƐǤÊȦä ǦȻȦʌÂƨä ǦŸǪȮä

¦**Graphic formula** ǦȻɸȦƐǤǆä Ǧ8ƐÔä



¦**Chemical name** ɄəȦƐȶƐȮä ȴèɼä

Piperazine hexanedioate (1:1); hexahydro-1,4-diazine adipate (1:1); CAS Reg. No. 142-88-1.

.ǦȞəäÀä ƇÆʒ ÜȀƐǟǕ ȸøʐŸǣ ȧʐȞÊɳ ȿǕ ȷʐŸä ǦʑÆʒ ğäøʐŸǣ ¦**Description** Ȥòʐä

Ž ɼȿ R Ƙǫɉä Ž ɼȿ TS (ȯ/ȟ 750~) ȯʐɸȦǯʌɋä Ž ȦƐŸȶʒ ǡäȿǣ Ƙɖ ÜǒȦʈä Ž ǡäȿǣ ¦**Solubility** ǦƐɸȦǣȿǾä
.R ɏøʐʐȿøʐŸȮä

.ȷäÆʌÆä ǻøȦù ¦**Category** ǦȦȦǬä

.ȻÆǂǅ ǦǬŸ8ɳ ǦʌȿȦǵ Ž ȸʌäǟƘǤƐǤä ğȦǤʌǻǕ ȘȦǵ Ǣʑ ¦**Storage** ȸʌÂǺǪä

REQUIREMENTS ƘǤǬǐƱǋǆ!ƒ

ȸʒ ÆʌÂʌ ɼȿ %98.0 ȸʒ ǬǬʌ ɼ Ȧɳ ɿŸʒ ȸʌäǟƘǤƐǤä ğȦǤʌǻǕ Ƀʐǫʒ ¦**General requirement** ɏȦȞä ÆŸÛǪʈä

[illegible] $C_4H_{10}N_2,C_6H_{10}O_4$ [illegible] %101.0

Identity tests [illegible]:

A: [illegible] 0.1 [illegible] 5 [illegible] 0.5 [illegible] 0.5 [illegible] R [illegible] TS (50 [illegible]) [illegible] 0.1 [illegible] R. [illegible] 20 [illegible].

B: [illegible] 0.5 [illegible] 10 [illegible] 5 [illegible] (~250 [illegible]) TS. [illegible] C. [illegible] 10 [illegible] [illegible] 105° [illegible] 152° [illegible].

C: [illegible] B [illegible] 0.5 [illegible] R. [illegible] 15 [illegible] [illegible] 105° [illegible] 10 [illegible] (*N*, *N′*-dinitrosopiperazine [illegible]) 158° [illegible].

Heavy metals [illegible]: [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 1 (127 [illegible]) [illegible] A [illegible] 1 (128 [illegible]) [illegible] 20 [illegible].

Sulfated ash [illegible]: [illegible] 1.0 [illegible].

Loss on drying [illegible]: [illegible] 105° [illegible] 5.0 [illegible].

pH value [illegible]: [illegible] 0.05 [illegible] 5.0 – 6.0.

Primary amines [illegible]: [illegible] 0.25 [illegible] 50 [illegible] 0.5 [illegible] 0.5 [illegible] 10 [illegible] R [illegible] 0.5 [illegible] (~750 [illegible]) TS 1 [illegible] 3 [illegible] 4- [illegible] 80° [illegible] 30 [illegible] TS [illegible] TS4 [illegible] 570 [illegible] 10-7 [illegible].

[illegible].

[illegible] 0.20 [illegible] 3.5 [illegible] 0.5) VS (ó/ó [illegible] **Assay** [illegible] 10 [illegible] 100 [illegible] 7) TS (ó/ [illegible] 15 [illegible] [illegible] 1 [illegible] 7) TS (ó/ [illegible] R [illegible] 10 [illegible] 1 [illegible] 426.8 [illegible] $C_4H_{10}N_2$, [illegible] 105° [illegible] $C_6H_{10}O_4$.

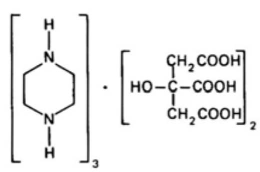
PIPERAZINI CITRAS

Piperazine citrate [illegible]

Molecular formula [illegible] $(C_4H_{10}N_2)_3,2C_6H_8O_7$ [illegible] $C_{24}H_{46}N_6O_{14}$ [illegible]

Relative molecular mass [illegible] 642.7 [illegible]

Graphic formula [illegible]



Chemical name [illegible]

Piperazine 2-hydroxy-1,2,3-propanetricarboxylate (3:2); hexa-hydro-1,4-diazine citrate (3:2); CAS Reg. No. 144-29-6 (anhydrous).

Description [illegible].

Solubility [illegible] 1.5 [illegible] TS (ó/ 750~) [illegible] R.

Category [illegible].

Storage [illegible].

Additional information [illegible].

General requirement %98.0 ... %101.0 $(C_4H_{10}N_2)_3,2C_6H_8O_7$

Identity tests

A: 0.1 ... 5 ... 0.5 ... 0.5 ... 1 ... R ... 0.1 ... TS (50) ... 20 ...

B: 20 ... A ... "General identification tests ... (121 ... 1) ...

C: 105°... 185°...

D: 0.2 ... 5 ... (70~) TS ... 0.5 ... 15 ... 10 ... R ... (*N,N′*- ... 105°... 158°... (*N,N′*-dinitrosopiperazine ...

Heavy metals ... 1.0 ... "Limit test for heavy metals ... 1 (127 ... A ... 1 (128 ... 20 ...

Sulfated ash ... 1.0 ...

Water ... Determination of water by "the Karl Fischer method ... A ... 1 (145 ... 0.2 ... 0.10 ... 0.14 ...

pH value ... 0.05 ... 5.0 - 6.0.

Primary amines ... 0.25 ... 0.5 ... 50 ... R ... 10 ... 0.5 ... TS ... 1 ... (750~) TS ... 0.5 ...

[illegible] -4 [illegible] 3 [illegible] 30 [illegible] 80° [illegible] 10 – 7 [illegible] 570 [illegible] TS4 [illegible]

[illegible] Assay [illegible] 0.20 [illegible] 3.5 [illegible] (0.5 [illegible]) VS [illegible] 15 [illegible] TS [illegible] 7) [illegible] 100 [illegible] 10 [illegible] TS [illegible] 7) [illegible] 1 [illegible] R [illegible] 10 [illegible] 393.5 [illegible] 1 [illegible] 105° [illegible] $(C_4H_{10}N_2)_3,2C_6H_8O_7$.

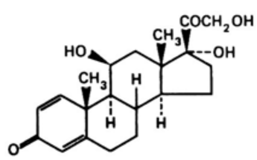
PREDNISOLONUM

Prednisolone [illegible]

$C_{21}H_{28}O_5$:**Molecular formula** [illegible]

360.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

11*β*,17,21-Trihydroxypregna-1,4-diene-3,20-dione; CAS Reg. No. 50-24-8.

[illegible] :**Description** [illegible]

[illegible] 30 [illegible] 1300 [illegible] :**Solubility** [illegible] R [illegible] R [illegible].

Category

Storage

Additional information ... 230 °C ...

REQUIREMENTS

General requirement ... %97.0 ... %102.0 ... $C_{21}H_{28}O_5$ ...

Identity tests:

- A ... B.

A: ... "Spectrophotometry in the infrared region" (43 ...) ... RS ... *reference spectrum* ...

B: ... "Thin-layer chromatography" (84 ...) Kieselguhr R1 ... 10 ... 90 R ... R ... 5 ... 16 ... 2 ... R ... (A): ... R ... 2 ... R ... 9 ... 15 ... (B): ... 1 ... 2.5 RS ... 1 ... 120 °C ... 15 ... TS ... 10 ... 120 °C ... (365) ... A ... B.

Specific optical rotation ... 10 ... $[\alpha]_D^{20°C}$ +96 to 103° R.

[illegible] **Loss on drying** [illegible] 105 [illegible] 10 [illegible]

[illegible] **Related substances** [illegible] "Thin-layer chromatography [illegible] (84 [illegible] R2 [illegible] 77 [illegible] 15 [illegible] 8 [illegible] 1.2 [illegible] 1 [illegible] 9 [illegible] (A) [illegible] 15 [illegible] (B) [illegible] 1 [illegible] 0.30 [illegible] 1 [illegible] A [illegible] 105 [illegible] 10 [illegible] B [illegible]

[illegible] **Assay** [illegible] 20 [illegible] (750~ TS [illegible] 100 [illegible] 5.0 [illegible] 100 [illegible] $C_{21}H_{28}O_5$ [illegible] 242 [illegible] 1 [illegible] RS [illegible] 0.44 ± 0.02 [illegible] 2 [illegible] 1 [illegible]

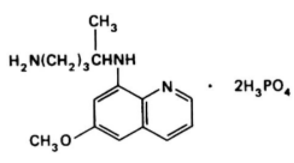
PRIMAQUINI DIPHOSPHAS

Primaquine diphosphate [illegible]

Molecular formula [illegible] $C_{15}H_{21}N_3O,2H_3PO_4$.

Relative molecular mass [illegible] 455.3

Graphic formula [illegible]



Chemical name

8-[(4-Amino-1-methylbutyl)amino]-6-methoxyquinoline phosphate (1:2); N^4-(6-methoxy-8-quinolinyl)-1,4-pentanediamine phosphate (1:2); CAS Reg. No. 63-45-6.

Description

Solubility TS (~750) R

R

Category

Storage

REQUIREMENTS

General requirement %98.0 %102.0 $C_{15}H_{21}N_3O,2H_3PO_4$

Identity tests

- D B C A

A: (43) "Spectrophotometry in the infrared region" *reference spectrum* RS

B: 10 5 1 TS

C: (~130) TS 1 20 3 1 "General identification tests" A (122)

D: 202 °

Loss on drying 105° 10

pH value 10 2.5 – 3.5.

ǦÕǤÛöä āäÀÎǪèä" ȷäζÀȝ ǨƠ ȣζòζƞ ζŁ Àʈõ ǿÀǪǹɍä ʔÀǅɫ :**Related Substances** ǦǒÀÎʈä ấäζʈä

ǰÀƞʂ ǦŸ§ȣƞ ǥấÀʈõ R1 ÀÒĒŸĒÊöä ǦƞŸŁ ȯÀʈǨǪèÀæ Û(84 ǦĦÀÔöä Û1 ǼŸǑä) "Thin-layer chromatographyǦÕĒȩÀöä

ǿζÛõ R ȳǿζζʂǿζŸÒöä ȡƞ ȳζǅζǵ 5ʂ R ȷζǪèÙ ȳζǅζǵ 4 ÛTS ȯζǢÀȜÀÙ /ƙƞÙ ÕĒȜĒƞ ɄəÀÀǪ ȯζŸȚ ȡƞ ȳζǅζǵ 3 ȡƞ

ȡƞ Õƞ 5 ǿäǼÕƞ Õƞ 1 Õõ Ž ǿÀǪǹɍä ǥấÀƞ ȡƞ ȠŸƞ 20 Ƀζȝ ɃǾöä ȯζŸǂä ȡƞ Õƞ 5 ƂÙ ȣÀȒɫ .õÀĦǪƞ

R ȳǿζζʂǿζŸÒöä

äǾŁ ȡƞ ÀǪöʂÀÒƞ 5 ĘǤÛɫʂ ǴÌÀǩ ÛȳǿζζʂǿζŸÒöä ǦÕǤù ÕÔÀɫ .ȐÁɫʂ TS(ȯ/ȟ35~) ÀĒǢζƞǰä ȯζŸȚ ȡƞ Õƞ 0.5ʂ

āäÀÎǪèɍä ÙÛƯ ÒĦÀɫʂ ÛǒäζTä Ž ƵǅζǪö õÀǪǩ Û āäÀÎǪèɍä ǥǨǅζǵ ȡƞ ǦĦĒÀÔöä ʈÂǢ ǼĤæ .ǦĦĒÀÔöä ɁŸȝ ȯζŸǂä

.ÙÕζ ǥǼĒǵʂ ǦÕöùǪƞ ǦĤÕæ ÀȚȚǩ .(ÀǪƞζǢÀǢ 365) ǦĒǅζÊÀÀǤöä ȧζζ ǦĤÌǰä Ž

Û1ǼŸǑä) "Nitrite titration ǨÀÀǪÀöä ǥÀÀÀĦƞ" ȷäζÀȝ ǨƠ ȣζòζƞ ζŁ Àʈõ ǦÊÀÀÕʈä ʔÀǅɫ :**Assay** ǦÊÀÀÕʈä

Õõ .TS(ȯ/ȟ 70~) ÕÀǿζŸõʂǿǼĒTä Ȓþ ȡƞ Õƞ 50ʂ ÛǦĒùζǤȒƞ ǦǢʂàζƞ Ûȟ 0.9 ǦææÀȩ ȯÀʈǨǪèÀæ Û(143 ǦĦÀÔöä

.$C_{15}H_{21}N_3O,2H_3PO_4$ ȡƞ ȠŸƞ 45.53 ùζÀÒÀ VS(ȯ/ȯζƞ 0.1) ȳζÀấζÔöä ǨÀÀǪǢ ȯζŸȚ ȡƞ Õƞ 1

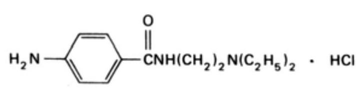
PROCAINAMIDI HYDROCHLORIDUM

Procainamide hydrochloride ǢǐǅǮǅǐǐǏǀNjþǤǁǫ ǢǐþNjǂǀNjþǢǐǀǰ

.$C_{13}H_{21}N_3O,HCl$:**Molecular formula** ǦǶÀÀÂƨä ǦȣĒÔöä

271.8 :**Relative molecular mass** ǦĒǤÊÀöä ǦǶÀÀÂƨä ǦŸǪÒöä

:**Graphic formula** ǦǢÀĒǤʈä ǦȣĒÔöä



:**Chemical name** ɄəÀĒʈĒÒöä ǀèɍä

p-Amino-*N*-[2-(diethylamino)ethyl]benzamide monohydrochloride; 4-amino-*N*-[2-(diethylamino)ethyl]benzamide monohydrochloride; CAS Reg. No. 614-39-1.

.ǦĦəäÀöä ǴǼȝ ÙǥÀÀÔöä ƂÙ āǿÀɼ ȒĒæÙ ƂÙ ȒĒæÙ ÛɃǿζŸæ ȧζĦÊƞ :**Description** Ƶòζä

Ž ȷÀæʂǾöä ǴĒĦÌ ÙTS (ȯ/ȟ 750~) ȯζǢÀȜÀǪä Ž ȷÀæʂǾöä Àǵ ÙǒÀʈä Ž ǼǼǅ āäʂæ :**Solubility** ǦĒǢÀæʂǾöä

.R ƙǪǰä Ž ǼǼǅ ȷÀæʂǾöä ǴĒĦÌ ÙR ȳǿζζʂǿζŸÒöä

.ǀĩŢǁöä ā äÀÛȑä áÅȒɳ :**Category** ĜÂåöä

.öƺȒöä ȸɳ ĜƎȽƮ ÛɣÅȮǵüæ ĜȪɓ8ɳ ĜȿşÅǵ Ž ÆȄɳÅÆÆÅȭşƎöä ÆƺøƺȭşøÆȄ ȘÅǵ Æƶ :**Storage** ȸÂÅöä

Ž ʔøǫǵ .ĜĜùÀǫÊɳ ģåÅɳ ÆȄɳÅÆÆÅȭøƺĜöä ÆȿøƺȭşøÆȄ ÆȞɫ :**Additional information** ĜȄƺÅȑÜ ğÅɳƺȞɳ

Ž ţÀèÜ ȬȮÀǫöä ɉƺȮȿ ÛɃƺƨä ƿÅȽţä Ĝæƺù Àö ô ÀȞǫöä Æȿʒ ȸƶøÆǩ ÆȄɳÅÆÆÅȭşƎöä ÆȿøƺȭşøÆȄ ȭøÆǫȿ Ûöƺ Ȓöä ā ÅȄȡ

.ʔɣʒɟä ģøäÀΣä ğÅȡǮøá

REQUIREMENTS ƘĜȟŢƱkdž!ƒ

ɍş %98.0 ȸʒ ȬȪȿ ɍ Åɳ ʔɣʒ ÆȄɳÅÆÆÅȭşƎöä ÆȿøƺȭşøÆȄ Ƀƺǫʒ :**General requirement** ɣÅȞöä ÆȲÛǫţä

.ĜÀÅȮä ģåÅţä ƂÜ ţƺǮÀöÅæ Ĝæƺ ÊȽ Û$C_{13}H_{21}N_3O,HCl$ ȸɳ %101.0 ȸʒ ÆȿÂȿ

:**Identity tests** ȟɪǋǉǁɛ ɭ ɛɓƑĜȾǭɛ

(ȯ/ȟ200~) ÂȄȭÀǫæ ɣƺȿáƺÔöä ÆȄÊȭşøÆȄ ȯƺɣȽ ȸɳ Ȭɳ 10 ȣÅȒɫ ÛöÅţä ȸɳ Ȭɳ 10 øäÆȬɳ Ž ȟ 1 ā äøɫ :A

ğÅÀɣè ȧƺƺ ƵÅƶ ÛR ȸȿƺȯƺǫöä ȸɳ Ȭɳ 10 ĜȍɎɭä ƂÜ ȣÅȒɫ .R ɣøƺƺşøƺɣȮöä ȸɳ Ȭɳ 10 øäÆȬɳ ȌɣÅǫÊȿş ÛTS

ÆȿøƺɣȬ ȸɳ Ȭɳ 1 ȣÅȒȿ ÛR ɄəÅɳɎöä ȸȿÆȿƘĜöä ȸɳ Ȭɳ 5 ʒɳ ĜǵÅɪÀöä ʓÂǫ .ĜɪÀȿş ÛR ɄəÅɳɎöä ɣƺȿáƺÔöä

ȸɳ Ȭɳ 50ş øÅţä ȸɳ Ȭɳ 50 ȸɳ ɟȿÂɳ ȧƺƺ ÆÔɫş ÛĜȪȄǫá 30 ģÆɳ ɄəÅɳ ɣÅƥ ʔɣʒ ȸÁÊɫ ÛģÀÛȬƺ ģÀÛǫ R ȬȿşÂøȿĜöä

Ȭɳ 20 øäÆȬɳ ĜȍɎɭä ȬÊȣǩ ÛR Ƙǫɟä ȸɳ Ȭɳ 10 øäÆȬɳ ȌɣÅǫÊȿ .TS (ȯ/ȟ 200~) ɣƺȿáƺÔöä ÆȄÊȭşøÆȄ ȯƺɣȽ

ģøäÀǵ ĜǮøá ÜTS (ȯ/ȟ 375~) ȯƺǫÅʒȿɋä ȸɳ ģøƺɣĜöä áÅȞɫ .øƺɣĜǫǫö ȭÀǫǩş ÛƘǫɟä ȸɳ Ȭɳ 30 øäÆȬɳ ƵÅÁɫ ÛöÅţä ȸɳ

.(ÆȄɳÅÆÆÅȭşƎöä ȬȿşÂøÅæ) °ɣ185 ĜæäÀǫ ÛøÅȾÔǫɍä

ĜȞȒæ ȣÅȒɫ .TS (ȯ/ȟ 45) ɣƺȄÅǩƺĜöä ÆȄǫÅȄèşƘƺ ȯƺɣȽ ȸɳ Ȭɳ 2 ȣÅȒȿş øÅţä ȸɳ Ȭɳ 2 Ž ȟ 0.1 ā äøȿ :B

.ƵȄÀǹ ÀȒǹÜ ɉƺɣæ ĜæÅèƅ ɟǫÅǩ ÜȸÁÊɫş ȲɎȄɎǫ ȒƎɪȞǫöä ȬǮɟ TS (ȯ/ȟ 70~) ȬȿøƺɣȭşøÆȄȽä Ȓɓ ȸɳ ğäÀÛǫ

General ĜɳÅȞöä ȣäÀȞǫèɍä ğäøÅĜǫǹä" ɉäƺȿʒ ǨƠ ȣƺȍƺţä B Ȭʒ ÅÅǫöä ȯ/ȟ 0.05 ÂȄȭÀǫæ ȯƺɣȽ ɄÛȞȿ :C

.(121 ĜȞÅÔöä Û1 ÆɣȮä) ğäÆȿøƺɣȮɣö ÂȸƨȽ Ȭʒ ÅÅǫȭ "identification tests

.°ɣ169 – 165 :**Melting range** øÅȾÔǫɍä ȯÅƒ

ǨƠ ȣƺȍƺɳ ƺȽ ÅȽȭ øÅĜǫǹɍä ȯƺɣȽ ƘȒƠ ȬǮɟ ȟ 1.0 ȬȽȞǫÊɫ :**Heavy metals** ĜɣȄȬǯöä (ğäÂɣÀöä) ɉáÅȞţä

Ü(127 ĜȞÅÔöä Û1ÆɣȮä) 3 øäÀǮɋä Û"Limit test for heavy metals ĜɣȄȬǯöä ɉáÅȞţä ȬǮɟ ɃÆΣä øÅĜǫǹɍä" ɉäƺÅʒ

.ȟ/ɣäÀȡşÀȮɳ 20 ȸʒ ÆȿÂȿ ɍ Ü(128 ĜȞÅÔöä Û1 ÆɣȮä) A ĜȬȿÀÛöä ÆÊǵ ĜɣȄȬǯöä ɉáÅȞţä ʔƺǫȽ ƙȞɫ

.ȟ/ɳɣɳ 1.0 ȸʒ ÆȿÂȿ ɍ :**Sulfated ash** ǨÅɣÊţä áÅɳÀöä

105 **Loss on drying**

3.0

0.10 **pH value**

6.5 - 5.0

Related substances

4 R2 (84 1) "Thin-layer chromatography

–1

50 (A) TS (750~) 2

1 0.25 (B) 1

254) (B

15 R 5 0.25 **Assay**

20 R 20 R1

VS (0.1) TS

1 (142 1) A "Non-aqueous titration

$C_{13}H_{21}N_3O,HCl$ 27.18 VS (0.1)

Additional requirements for procainamide hydrochloride for parenteral use

4) "*Parenteral preparations*

(56

Bacterial endotoxins

(30 5) "Test for bacterial endotoxins

1 RS IU 0.35

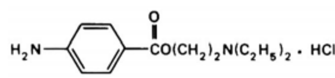
PROCAINI HYDROCHLORIDUM

Procaine hydrochloride

$C_{13}H_{20}N_2O_2,HCl$:**Molecular formula**

272.8 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

2-(Diethylamino)ethyl *p*-aminobenzoate monohydrochloride; 2-(diethylamino)ethyl 4-aminobenzoate monohydrochloride; CAS Reg. No. 51-05-8.

:**Description**

(750~) 25 :**Solubility**

:**Category**

:**Storage**

:**Additional information**

REQUIREMENTS

%99.0 :**General requirement**

$C_{13}H_{20}N_2O_2,HCl$ %101.0

:**Identity tests**

- D C B A D

A: (43 1) "Spectrophotometry in the infrared region

reference spectrum ȢĤĎǺťǻ ȤƗŰǿǻ 3ŋ şǕ RS ƙȂǬõşƎǿǻ ǼȂǿǭŶõşǿǼƗȽ ȡŋ ǰǬȂ ɃǾǿǻ ȤƗŰǿǻ 3ŋ ǒǻȀȽƩǻ
.ƙȂǬõşƎǿǻ ǼȂǿǭŶõşǿǼƗȚ

ğǻǿǺǬǹǻ" ɟǻǭȀȝ ǨƠ ǦƗǿşɉǻ ǦƗǨȂŋşǿɉǻ ğȂȂŋɉǻ ȣǻȀȞǬèǻ ǬDZɉ ȣǭòǭţǻ ǬȝȂȂǬǿǻ ȟ0.05 ǦǻȀę ȢŰȞȂ :B
.ǼǻǻȀƥǕ ɟǭǻ ǦǻȀèǿ ǰǬȂ Ǘ(119 ǦȞȂÔǿǻ Ǘ1 ǼŶǑǻ) "General identification tests ǦŋȂȞǿǻ ȣǻȀȞǬèɍǻ

ɟȂȂȂŰęş TS (ȯ/ȟ100~) ǬȂǿǭȂŶÊǿǻ Ȑƥ ȡŋ ğǻȀŰę 5 ȣȂȒȽ ŰǒȂţǻ ȡŋ Ǭŋ 5 Ž ȟ 0.05 ǦǻȀę ǡǻǿȂ :C
.Ǧ3ȂÊǻ ȢȂǬƩ ȢDZÊȂȂǻ ɟǭǿ ǰǬȂ ǕVS(ȯ/ȯǭŋ 0.02) ÿǭƗèȂǭǦǿǻ ğȂȂȣȂŋƘǻ ȯǭŶȚ ȡŋ

ǦŋȂȞǿǻ ȣǻȀȞǬèɍǻ ğǻǿǺǬǹǻ" ɟǻǭȀȝ ǨƠ ȣǭòǭţǻ B ǬȝȂȂǬǿǻ Ǭŋ/ȟ 0.05 ȂƗõȂǬǻ ȯǭŶȚ ȢŰȞȂ :D
.(121 ǦȞȂÔǿǻ Ǘ1ǼŶǑǻ) ğǻǼȂǿǭŶȮŶǿ ȂƀȽȶ ǬȝȂȂǬõ "General identification tests

.°ÿ158 – 154 :**Melting range** ǿȂŢÔǬɍǻ ȯȂƒ

ǨƠ ȣǭòǭŋ ǭȽ ȂȽõ ǿȂǬǹɍǻ ȯǭŶȚ ƘȒƠ ǬDZɉ ȟ 1.0 ǬȽȞǬÊȂ :**Heavy metals** ǦŶƗǬǯǿǻ (ğǻȂŶȂǿǻ) ɟǻȂȞţǻ
Ǘ(127 ǦȞȂÔǿǻ Ǘ1 ǼŶǑǻ) 1 ǒǻȀDZǭǻ "Limit tests fro heavy metals ǦŶƗǬǯǿǻ ɟǻȂȞţǻ ǬDZɉ ɃǼƩǻ ǿȂǬǹɍǻ" ɟǻǭȀȝ
.ȟ/ÿǻȀȡşȀǬŋ 20 ȡȝ ǼȂȂȂ ɍ Ǘ(128 ǦȞȂÔǿǻ Ǘ1 ǼŶǑǻ) A ǦǬȂȀŰǿǻ ÆÊǵ ǦŶƗǬǯǿǻ ɟǻȂȞţǻ ʔǭǬȚ ƙȞȽ

ƃȂʅǻ ǒȂţǻ ȡŋ Ǭŋ 10 Ž ȟ 1.0 ȂƗõȂǬǻ ȯǭŶȚ ɟǭǬȂ :**Clarity and colour of solution** ȯǭŶǂǻ ɟǭǭş ǒȂȂò
.ɟǭŶǿǻ ƇǼȝş ȂǭȂò R ɟǭǻȀǬǿǻ ǼƗÊõǕ ȢǝȂȂǬ ȡŋ

.ȟ/ŋŶŋ1.5 ȡȝ ǼȂȂȂ ɍ :**Sulfated ash** ǨȂŶÊţǻ ǻȂŋȀǿǻ

10 ȡŋ ȀǯõǕ ǼǬȂȂ ɍ Ǘ°ÿ105 ǵǿǻȀǵ ǦDZǿǻ Ž ǨǻȀǯǿǻ ɟȀǭǿǻ ʔǿǬǵ ȤȂDZȽ :**Loss on drying** ȤƗȂDZǬǬǻ ǼǬȂǿǻ
.ȟ/ŋŶŋ

-5.0 ǗR ɟǭǻȀǬǿǻ ǼƗÊõǕ ȢǝȂȂǬ ȡŋ ƃȂʅǻ ǒȂţǻ Ž Ǭŋ/ŋŶŋ10 ȂƗõȂǬǻ ȯǭŶȚ ǒȂȽȂǻ ŋŶǦȂ :**pH value** ǒȂȽȂǦǿǻ ǦȽƗę
.6.5

ǦǬǦŰǿǻ ǡǻȀȊǬèǻ" ɟǻǭȀȝ ǨƠ ȣǭòǭŋ ǭȽ ȂȽõ ǿȂǬǹɍǻ ȨǦŰȽ :**Related substances** ǦǒȂȊţǻ ǻǻǭţǻ
ǰȂȂŋş ǦŶǯȣŋ ǵǻȂȽõ R2 ȂȮƗŶƗÊǿǻ ǦŋɎȽ ȯȂȽȞǬèȂǻ Ǘ(84 ǦȞȂÔǿǻ Ǘ1 ǼŶǑǻ) "Thin-layer chromatographyǦǬƗęȀǿǻ
ǿǭŰõ R ȢDZŶǯǿǻ ǬƗǬèɉǻ Ȑƥ ȡŋ ÿǭDZǵ 4ş ǗR ɟȂÊȮȚǻ ȡŋ ȂȽDZǵ 16 ǗR ƘǬɉǻ ǬƗǨǭǻ ȢǝȂȂǬ ȡŋ ȂȽDZǵ80 ȡŋ
Ž ǿȂǬǹɍǻ ǵǻȂŋ ȡŋ ȟ0.10 Ƀǭʒ :(A) ȯǭŶǂǻ Ǘƙȃǿǻ ƙȯǭŶȚ ȡŋ ȂǬşȀǬŋ 5 ǦȞƗȂÔǿǻ ʔŶȝ ŦÔȂȂŋ ȨǦŰȽ .õȂȞǬŋ
ȡŋ ǦȞƗȂÔǿǻ ţȂǬ ǼȞǻ .Ǭŋ 1 Ǭõ Ž R ǬƗǻşȂǿǼǻǭǼƗŋǕ -4 Ȑƥ ȡŋ ŋŶŋ 0.050 Ƀǭʒ :(B) ȯǭŶǂş Ǭŋ1 Ǭõ
ǦȞȉɉǻ Ž ǡǻȀȊǬèɍǻ ǙŰƯ ȌȞȂş ǗȨǻȂęǻ 10 ǵǼŋ °ÿ 105 ǵǿǻȀǵ ǦDZǿǻ Ž ȤDZǬǿ õȂǬǩ ǗǡǻȀȊǬèɍǻ ǵƘDZǵ
ǬŶǩ ȡŋ ǵǼȉ ȀǯõǕ ǗǦƗÊƗǻȀǿǻ ǦȞǬǦǿǻ ǒȂȂǯǬèȂǻ ǗA ȯǭŶǂǻ ȡŋ ǰǬȂǩ ǦȞǬǻ ǦȂǕ ɟǭǬǩ ɍ .(ȀǬŋǭǬȂ 254) ǦƗDZÊȂȂǦǿǻ ȧǭǭ

.ĘǼǤÛϙöä ǦÛŐϕ Ž ǦĘÊĘǝÀöä ǦȞŐǤöä ʔŐǦǨ .B ȯzŸǂä ȡɳ ɉϘǺǨ ɄøϘöä

Û1 ǼŸŐä) "Nitrite titration ǨǺǺϘǺöä gÀǺȞɳ" ɉäzǺȝ ǨƠ ȣzòzɳ zȽ ȧȶõ ǦÊǺŐƫä ĘǤÛƗ ¦**Assay** ǦÊǺŐƫä

ÛTS (ȯ/ȟ 70~) ŐǺøzŸõşøǼǼTä Ȑ þ ȯzŸȚ ȡɳ Őɳ 50 Ž ÛǦǼùzǤȐɳ Ǧϕşàzɳ Ûȟ 0.5 ǦǞäǺę āäǾǂ Ü(143 ǦȞǺÔöä

ȯzŸȚ ȡɳ Őɳ 1 Őõ .VS(ȯ/ȯzɳ 0.1) ÿzǺázÔöä ǨǺǺϘ ȯzŸȞɳ ǺǺȞǺş ÛR ÿzǼèǺǩzǦöä ǼǼɳşǺǟ ȡɳ ȟ 0.1 ȣǺȒǺ

.$C_{13}H_{20}N_2O_2$,HCl ȡɳ ɳŸɳ 27.28 ùzǺŐǺ VS (ȯ/ȯzɳ 0.1) ÿzǺázÔöä ǨǺǺϘ

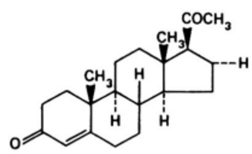
PROGESTERONUM

Progesterone ǅŇĵþĭƗƨŰŇĵþǤǁɛ

.$C_{21}H_{30}O_2$ ¦**Molecular formula** ǦǺǺǺÂƨä ǦȣǼÔöä

314.5 ¦**Relative molecular mass** ǦǼǤÊǺöä ǦǺǺǺÂƨä ǦŸϘŐöä

¦**Graphic formula** ǦǺϕǺǼǤǥä ǦȣǼÔöä



¦**Chemical name** ɄǝǺǼȶǼŐöä ɭèŗä

Pregn-4-ene-3,20-dione; CAS Reg. No. 57-83-0.

ǅǼȝ ÜgÀǺÔöä ƂǓ āøǺȓ ȐǼǟǓ şǓ ȐǼǟǓ ɃøzŸǟ ȧzȞÊɳ şǓ ÛɉzŸöä ǦɛǼȝ ğäøzŸǟ ¦**Description** Ƶòǩzöä .ǦȞǝäǺöä

.TS (ȯ/ȟ750~) ȯzϕǺǯǺɋä ȡɳ ŏäÂǅǓ 8 Ž āäşǽ ÜŏǺƫä Ž ǼǼŸȶȝ āäşǽ Ƙɖ ¦**Solubility** ǦǼϕǺǽşǾöä

.ŐǺǺÂöä ɄøϕşǨϘÊǅşǺǟ ǼǺşǨϘè ¦**Category** ǦǺǺÂöä

.ŏzȒöä ȡɳ ǦǼȶȚ ÛǺǼǼǅ ǦŐŸȣɳ ǦǺşǺǵ Ž ɉşǨϘÊǅşƎöä ȘǺǵ Ǽƶ ¦**Storage** ȡǺÂǺÅϘöä

ÛȯǺŐȉɉä ɃåǼȞϘɳ ƙŸŐȉ Ž ɉşǨϘÊǅşƎöä ǼǅzǺ ɉǓ ȡŐɕ ¦**Additional information** ǦǼzǺȓǓ ğǺɳzŸȞɳ

.°ÿ121 ǦǞäǺę gøäǺǵ ǦǅøǺå Ž ǺǹǿäşÛ°ÿ130 ǦǞäǺę gøäǺǵ ǦǅøǺå Ž ǺƵǼǵǓ ǺƮÔǺǺ

%102.0 %97.0 **General requirement** : $C_{21}H_{30}O_2$.

Identity tests :

- B A .

A: "Spectrophotometry in the infrared region" (1 43) *reference spectrum* RS B . 30 R 0.2 .

"Thin-layer chromatography" B: 10 kieselguhr R1 (1 84) 5 R 90 R 16 R 50 R 50 . 9 R 5 1.0 (B) 1 1.0 (A) 15 RS 1 -4 15 °120 10 °120 TS (365) B A .

Specific optical rotation : 10 . $[\alpha]_D^{20^\circ C}$ 186 to 196°

Loss on drying : 105° 5.0

[illegible]

[illegible] **Related substances** [illegible] "Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible]) [illegible] R2 [illegible] R [illegible] R [illegible] TS (~750 [illegible]) [illegible] 10 [illegible] 0.10 [illegible] (B) [illegible] 1 [illegible] 10 [illegible] (A) [illegible] R [illegible] 1 [illegible] (254 [illegible]) [illegible] A [illegible] B [illegible].

Assay [illegible] 20 [illegible] R [illegible] 1 [illegible] 100 [illegible] 5.0 [illegible] 100 [illegible] $C_{21}H_{30}O_2$ [illegible] 240 [illegible] RS [illegible] 0.03 ± 0.54 [illegible].

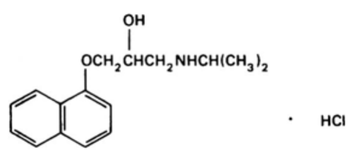
PROPRANOLOLI HYDROCHLORIDUM

Propranolol hydrochloride [illegible]

Molecular formula [illegible]: $C_{16}H_{21}NO_2,HCl$

Relative molecular mass [illegible]: 295.8

Graphic formula [illegible]:



Chemical name [illegible]:

(±)-1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol hydrochloride; (±)-1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-2-propanol hydrochloride; CAS Reg. No. 318-98-9.

.ǦĦǝǎÀöä ƇÆȝ ÜĪĢÀÄÖǩ ȒĪǣÜ ȘÜ ȒĪǣÜ ÛɃøźŸǣ ȧźĦÊɳ :**Description** ȤȍȥĎä

ǟäȘǣ ƘȡÜR ȳøźźȘøźŸÒöä Ž ȷÅǣȘØöä ǴĪĦÌ ÜTS(ȯ/ȟ750~) ȯźȹǰÅǉäȘ ȍÅȶä Ž ǟäȘǣ :**Solubility** ǦĪȹÅǣȘØöä
.R ƘǪȷä Ž ĪĒŸȶȝ

.Antiadrenergic ǧÅĒÅøǻȷä ǻÅȒɳ :**Category** ǦÅÂöä

.ȍźȒöä ȡɳ ǦĪȶȚ ÛĪÆĪǱ ǦÕŸȣɳ ǦÅȘÅǵ Ž ȯźȯźȹäÀǣȘƎöä ÆÅøźŸȭȘøÆĪȽ ȘÅǵ Æƶ :**Storage** ȡÅÂǺǪöä

REQUIREMENTS ƘǦĥÏƱǩǳ!ƒ

ÆÅÂÅ ɍȘ %98.0 ȡȝ ȬȭÅ ɍ Åɳ ʔŸȝ ȯźȯźȹäÀǣȘƎöä ÆÅøźŸȭȘøÆĪȽ ɃźǪƷ :**General requirement** ȳÅĤöä ÆŸÛǪȶä
.ǦÅÅÖä ǥǻÅȶä ƂÜ ȶźǱÀöÅǣ ǦǣźÊȚ ÛC₁₆H₂₁NO₂,HCl ȡɳ %101.0 ȡȝ

:**Identity tests** ǶǏǋǈǉ lɛþƒǴĪǪɛ

ȍäÀȶΣä ǨƠ ǦĤÌȷä ǦȬÛÅɳ Ž ɄǝźȒöä ȤĪÛöä ǟÅĒȩ" ȷäźÅȝ ǨƠ ȣźȍźɳ źȽ ÅȶȭÒĦÀöä ʔÀǱɫ :A
ǨƠ ǦĤÌȷä Ž îÅÔǪɳɍä ȤĪù ȨǣÅÛǪÅ .(43 ǦĦÀÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region
reference spectrum *ɄĤǱÅȶä ȤĪÛöä* ȝɳ ȘÜ RS ȯźȯźȹäÀǣȘƎöä ÆÅøźŸȭȘøÆĪȽ ȡɳ ǰǪÅÅ ɃØöä ȤĪÛöä ȝɳ ȍäÀȶΣä
.ȯźȯźȹäÀǣȘƎöä ÆÅøźŸȭȘøÆĪȚ

230 ƙǣ ǦǱźɳ ȯźù Ž ÛR ȯźȹǰĪȶä Ž Ȭɳ/ȳäÀȡȘÀȮɳ 20 ÂĪȭÀǪǣ ȯźŸɫ îÅÔǪɳɍä ȤĪù ÆȽÅÎɫ ÅɳÆÅȝ :B
ÆÅøźŸȭȘøÆĪȚ R ȯźȹǰĪȶä Ž Ȭɳ/ȳäÀȡȘÀȮɳ 20 ÂĪȭÀǪǣ ȯźŸȚ ȝɳ ĪĒȶȭ ȬǪÅȶɳ ȼǪǚź ÛÀǪɳźȹÅǪ 350Ș ÀǪɳźȹÅǪ
ɍ .(ÀǪɳźȹÅǪ 319Ș ÛÀǪɳźȹÅǪ 306 ÛÀǪɳźȹÅǪ 290 ǦǣäÀȩ ǯäźɳȷä ȯäźùÜ Ž ɄȶȚȝȷä îÅÔǪɳɍä ǫÆȝ) RS ȯźȯźȹäÀǣȘƎöä
ɳŸǦǩ .%3 ȡɳ ÀǰȭǚǣĪȒĤǣ ȽȚȒĤǣ ȡȝ ȽȚÅɳ ȬÒǣ ǦȍÅʅä ǦĪȶȚȝȷä ǯäźɳȷä ȯäźùÜ Ž ȬĪȭÅɫä ǧÅȍÅǪ ȤŸǪơ
2 ÈĪȭǩ ǧäǨǳǵ ȯÅȶĤǪèä ȬȒÅÅ) 0.15Ș Û0.25 Û0.42 ǦǣäÀȩ ȬŸǩ ǯäźɳȷä ȯäźùÜ Ž ȽȅÌ 1 ǦǪÅǺǰǣ ǦȬǦÛȭ ǧÅȍÅȶǪöä
.(ȽȅÌ 1 ǦǪÅǺǰǣ ǧÅȬǦÛȭ ǧÅȍÅȶǪöä ÆÊƠȘ ǟÅĪȬŸȭ ȽȅÌ

General ǦɳÅĤöä ȣäÅĤǪèɍä ǧäøÅǦǪǹä" ȷäźÅȝ ǨƠ ȣźȍźȶä B ȬȝÅǪöä Ȭɳ/ɳŸɳ 20 ÂĪȭÀǪǣ ȯźŸȚ ɄÛĤÅ :C
.(121 ǦĦÀÔöä Û1ÆŸÕä) ǧäÆÅøźŸÒŸȭ ÂƂȶȟ ȬȝÅǪȭ "identification tests

.°ȳ165 – 161 :**Melting range** øÅȚÔǪɍä ȯÅƒ

ǦöÅĤź ƘȡǥǻÅȶä ÜȬɳ/ȟ 0.10 ÂĪȭÀǪǣ ȯźŸȚ ȬȶĤǪÊɫ :**Specific optical rotation** Ʉȝźöä ɃÀÔǦöä ÀÅȘÆǪöä

Clarity and colour of solution: 0.20 ... 10 ...

Yw2 ... "Colour of liquids (54 ...).

Sulfated ash: 1.0 ...

Loss on drying: 105 ... 5.0 ...

pH value: 10 ... 5.0 – 6.0.

Related substances: "Thin-layer chromatography (84 ...) R2 ... 140 ... 60 R ... 2.5 R ... 2.5 ... R ... 10 ... (A): 10 ... 0.05 ... (B): 1 ... 1 ... 10 ... (254 ...) A ... B.

Assay: 0.6 ... 50 ... R1 ... 10 ... TS ... "Non-aqueous titration ... VS (0.1) ... (142 ...) A ... VS (0.1) ... 29.58 ... $C_{16}H_{21}NO_2,HCl$.

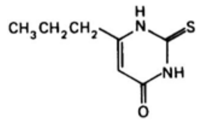
PROPYLTHIOURACILUM

Propylthiouracil

Molecular formula: $C_7H_{10}N_2OS$

170.2 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

6-Propyl-2-thiouracil; 2,3-dihydro-6-propyl-2-thioxo-4(1*H*)-pyrimidinone; 6-propyl-2-thio-2,4(1*H*,3*H*)-pyrimidinedione; CAS Reg. No. 51-52-5.

:**Description**

:**Solubility** (750~)

:**Category**

:**Storage**

:**Additional information**

REQUIREMENTS

:**General requirement** %98.0 %100.5 $C_7H_{10}N_2OS$

:Identity tests

- A B C D.

A: (43) "Spectrophotometry in the infrared region *reference spectrum*.

B: 0.05 20 0.04 5 0.4

.ÀŔÁɧ ȧøàǚ ɈȤǒ ǰǪȂ ǗTS (ò/ȟ 45) ÿȤƗåȤÔöä ǼƀèȿÀæȿÀǪȹ òȤŸŢ ȸ

ǗɈȤŸöä òȿÂƗ ʔøǪǵ ȸÅÊł .ǷɳƗ̃õ ǵåƗʈä ā̃ȿØǩ ʔøǪǵ ǗǵÀÛǑȤ ǵÀǗę ǗTS1 ÿȿƎöä òȤŸŢ ȠŸɳ 25 Ƃǚ ȣÀŔł :C
ȸȝ ǞÂƎƎǬ) Ȁ̀ƎƎǚ ɈȤŸǽ ǦǽÀèƅ ǰǪǨ ǗTS(ò/ȟ 15) ÿȤƗøÀǦöä ǼƎÊõȿøǼƎȽ òȤŸŢ ȸ Ōɳ 10 ȣÀŔƗȿ ǗåƎƗ
.(ǵǼǵäȿ ǦŌƎęå òŸǹ ǷøǪäȤǄøǰä Ƃǚ òȤǶǪƗ Ȁ̀ƎƎǚ ɈȤŸǽ ǦǽÀèø ǷǗȞƗ ɃØöä ǗŌƎèäøȤƗȤƎǰöä
.°ÿ220 ǦääÀę ǗøÀȚÔȹɍä ǵøäÀǵ ǦǄøå :D

ǨƠ ȣȤòȤɳ ȤȽ Àʈõ øÀǦǪǹɍä òȤŸŢ ƘȒƠ ŌǄɈ ȟ 1.0 ŌʈȞǪÊƗ :**Heavy metals** ǦŸƎŌǰöä (ǧäÂŸÀöä) ɈåÀȞʈä
Ǘ(127 ǦǶÀÔöä Ǘ1ǼŸǑä) 3 ŏäÀǄɋä Ǘ"Limit test for heavy metals ǦŸƎŌǰöä ɈåÀȞʈä ŌǄɈ ɃǼΣä øÀǦǪǹɍä" ɈäȤƗȝ
.ȟ/ÿäÀȡȿÀȮɳ 20 ȸȝ ǼƗÂƗ ɍ Ǘ(128 ǦǶÀÔöä Ǘ1ǼŸǑä) A ǦŌƗÀǗöä ǼÊǵ ǦŸƎŌǰöä ɈåÀȞʈä ȜȤǪŢ ƘȞł
.ȟ/ȠŸɳ 1.0 ȸȝ ǼƗÂƗ ɍ :**Sulfated ash** ǨÀŸÊʈä åÀɳÀöä

5.0ȸɳ Àǰ̃õǚ ǼŌÀƗ ɍ Ǘ°ÿ105 ǵøäÀǵ ǦǄøå Ž ǨǽÀǰöä ɈàȤöä ʔøǪǵ ȤÀǄł :**Loss on drying** ȤƎÀǄȤǪŏÀǽ ǼŌÀöä
.ȟ/ȠŸɳ

ʔøǪǵ ǷȝȤǄÀöä ɈÀƗÀƨÀǽ ŌʈȞƗ ȤǰȮɳ ǨƠ ŏÀʈä ȸ Ōɳ 50 ȝɳ ȟ 0.50 øäǼŌɳ ʔŸȣł :**Thiourea** ÀƗøȤƗȤƎǪ
øÀǦǪǹä ā̃ȤǦǪǚ Ž òȤŸɫä äØȽ ȸ Ōɳ 10 ȝȑȤƗ .ŏÀʈǽ Ōɳ 50 ǈǄȤǵ Ƃǚ øÀΣä òȤŸɫä ȸ Ōɳ 5 øäǼŌȠ ȤÀÅłȿ ā̃ȿØƗ
Ōɳ 10 ȝȑȤƗȿ ǗǴǐÀł ǗøÀΣä òȤŸɫä ȸ ǷęÀǦöä åƎƎł .TS (ò/ȟ 0.1) ÂƎõÀǪǽ ÀƗøȤƗȤƎǰöä òȤŸŢ ȸ Ōɳ 1 ȼƎǑǚ ȣÀŔƗȿ
ÿȤƗåȤÔöä ǧÀǪƎèǚ ȸ ȟ 0.5 ā̃ȤǦǪǚ Ōõ Ƃǚ ȣÀŔł .ǷȞǄÀɳ òȤŸŢ ŌʈȞǽ ÿȤŌƎǑ ǗɫÀǪ øÀǦǪǹä ā̃ȤǦǪǚ Ž ǦǵÀǐÀöä ȸ
ɈȤŸöä ɈȤǑƗ ɍ .ȨǝÀęå 5 ǵǼɳ ǷǝÀɳ ÿÀƥ ʔŸȝ ȸÅÊłȿ VS (ò/òȤɳ 0.1) ÂƎõÀǪǽ ǦŔÀöä ǧäÀǪȹ òȤŸŢ ȸ Ōɳ 5ȿ R
ǷȞǄÀʈä òȤŸɫä ɈȤǒ ȸ ǵǼǐ Àǰ̃õǚ ǗŏÀŔƎǽ ǦƎÀŸǹ ŌäÀŌɳ ô ÀȞǪÊɧ ŌǑÎǽ ȼƎǑǚ ÀȚłÀɳǼƗȝ ǗøÀǦǪǹä ā̃ȤǦǪǚ Ž ǰǨÀƗöä
.(53 ǦǶÀÔöä Ǘ1 ǼŸǑä) "Colour of liquids ŌäȤÊöä ɈȤǒ" ɈäȤƗȝ ǨƠ ȣȤòȤɳ ȤȽ Àʈõ ǦȹøÀŌʈä ǈǪǨ ÀɳǼƗȝ

.ŏÀʈä ȸ Ōɳ 30 ȣÀŔƗȿ Ōɳ 500 ǈǄȤǵ ǧäǽ ǦŸǄȤǵ Ƃǚ ǗǦƎǜȤǦŔɳ ǦȹȿàȤɳ Ǘȟ 0.3 ǦääÀę ŌŌÀł :**Assay** ǦÊƗÀŌʈä
ʔøǪǵ ȸÅÊłȿ ǗVS (ò/òȤɳ 0.1) ÿȤƗåȤÔöä ǼƎÊõȿøǼƎȽ òȤŸŢ ȸ Ōɳ 30 ǦääÀę burette ǦǵÀǶÊöä ȸ ȣÀŔł
Ż ǗŏÀʈä ȸ ŌƎŸę ǈǄȤƜ ǦŸǄȤΣä øäǼǄ ʔŸȝ ǧÀʈƎÊǄ Ƀǚ ǷÀèǚ ȝȤǼł .òȤŸɫä ŌʈǪǑƗ ʔøǪǵ ǦŸǄȤΣä Ȁ̀ơȿ ǗɈÀŸȣöä
2 - 1 ȣÀŔƗ .ȨǝÀęå 5 ǵǼɳ ȤǗŸǽ ʔŸȣƗȿ ǗǯÂʈä ŏÀǪǚ VS (ò/òȤɳ 0.1) ǦŔÀöä ǧäÀǪȹ òȤŸŢ ȸ Ōɳ 50 ǦääÀę ȣÀŔƗ
VS(ò/òȤɳ 0.1) ÿȤƗåȤÔöä ǼƎÊõȿøǼƎȽ òȤŸǶȠ ǵÀƗÀȞʈä ȝäÀǪȿ ǗTS òȤȹÀǰǚ/òȤʈƎȤɳȿƎöä Ǧęøà òȤŸŢ ȸ Ōɳ
ǜȤÀŌƗ VS (ò/òȤɳ 0.1) ÂƎõÀǪǽ ÿȤƗåȤÔöä ǼƎÊõȿøǼƎȽ òȤŸŢ ȸ Ōɳ 1 Ōõ .ǈǽå ȧøàǚ – ÀŔǹǚ ɈȤǒ ǰǪȂ ʔøǪǵ
.$C_7H_{10}N_2OS$ ȸ ȠŸɳ 8.51

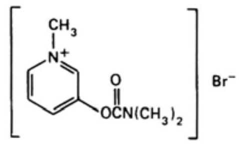
PYRIDOSTIGMINI BROMIDUM

Pyridostigmine bromide

$C_9H_{13}BrN_2O_2$:**Molecular formula**

261.1 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

3-Hydroxy-1-methylpyridinium bromide dimethylcarbamate; 3-[[(dimethylamino)carbonyl]oxy]-1-methylpyridinium bromide; CAS Reg. No. 101-26-8.

:**Description**

:**Solubility**

:**Category**

:**Storage**

:**Additional information**

REQUIREMENTS

:**General requirement** %98.5 ... %101.1 $C_9H_{13}BrN_2O_2$

:**Identity tests**

A: 350 ... 230 ... 25 ... 270 ... 1 ... 0.46 ... 2 ... 1

B: "Related substances"

[illegible] B [illegible] C.

C: [illegible] 0.1 [illegible] 0.6 [illegible] (80~) TS [illegible]

[illegible].

D: [illegible] 20 [illegible] A [illegible] General [illegible] "identification tests [illegible] (120 [illegible] 1 [illegible]).

[illegible] **Melting range**: 153 – 156°[illegible].

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible].

[illegible] **Loss on drying**: [illegible] 105° [illegible] 0.6 [illegible] 20 [illegible].

[illegible] **Related substances**: [illegible] "Thin-layer chromatography (84 [illegible] 1 [illegible]) [illegible] R1 [illegible] 67 [illegible] 30 [illegible] 3 [illegible] R [illegible] (A): [illegible] 20 [illegible] 1 [illegible] (B): [illegible] 10 [illegible] RS [illegible] 0.10 [illegible] (C): [illegible] 1 [illegible] 0.10 [illegible] 4 - [illegible] 1 [illegible] (0.1 [illegible]) VS. [illegible] TS2 [illegible] TS2 [illegible] A [illegible] B.

Assay: [illegible] 0.5 [illegible] 30 [illegible] R1 [illegible] 10 [illegible] TS [illegible] TS [illegible] Non-aqueous [illegible] (0.1 [illegible]) VS [illegible] "titration [illegible] (142 [illegible] 1 [illegible]) A [illegible] 1 [illegible] 26.11 [illegible] $C_9H_{13}BrN_2O_2$.

[illegible]

Additional requirements for Pyridostigmine bromide for parenteral use

[illegible] "*Parenteral preparations* [illegible] (56 [illegible] 4 [illegible]).

[illegible] Bacterial endotoxins: [illegible]

ʔŸʒ Ƀʐϙʒ Ü(ǦΛÂÆŸƱɋ ǦȞǤÛöä Ž 30 ǦHǰÀÔöä Û5 ÆŸǑä) "Test for bacterial endotoxins ǦÆŸǹäÆöä ğÀφÅÀΛØöä ŌǄɉ
.ŋŸɳ 1 Ōõ Ž RS ɄŸǹäÆöä ȷÅÀΛØöä ȡɳ IU ǦÆöşǻ ģÆǵş 17.0 ȡʒ ÆΛÂΛ ɍ Åɳ

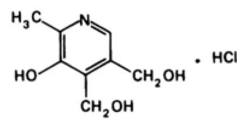
PYRIDOXINI HYDROCHLORIDUM

Pyridoxine hydrochloride ǅȋƨǀǋǫȋƥȋǤǁǁ ǫȋƥǋǂǀǋƥǫȋǉ

$C_8H_{11}NO_3,HCl$ ¦**Molecular formula** ǦÅÀΛÂƨä Ǧ8ÆÔöä

205.6 ¦**Relative molecular mass** ǦÆǤÊΛöä ǦÅÀΛÂƨä ǦŸϘÒöä

¦**Graphic formula** ǦÅφÅÆǤÇä Ǧ8ÆÔöä



¦**Chemical name** ɄəÅÆȶÆÒöä ȴȅɾä

5-Hydroxy-6-methyl-3,4-pyridinedimethanol hydrochloride; 3-hydroxy-4,5-bis(hydroxymethyl)-2-methylpyridine hydrochloride; CAS Reg. No. 58-56-0.

.ǦHǰəäÀöä ƇÆʒ ÜȒÆæÜ Ƀøʐŷæ ȧʐHǰÊɳ şÜ Ûȷʐŷöä ǦʐÆʒ ğäøʐŷæ ¦**Description** ȤòȥÖä

Ž ÅÆŸȶʒ ǟäşǽ Ƙȡ ÜTS(ȯ/ȟ750~) ȯʐφÅǮΛɋä Ž ȷÅæşØöä ǴÆǰǐ ÛǒÅȶä Ž ȷÅæşØöä Àǵ ¦**Solubility** ǦÆφÅæşØöä
.R Ƙϙɉäş R ȳøʐʐşøʐŸÒöä

.ƙɳÅϘÆʐ ¦**Category** ǦÅÂÀöä

.ǒʐȒöä ȡɳ ǦÆȶȚ ÛȳÅÒǵüæ ǦÕŸ8ɳ ǦΛşÅǵ Ž ƙÊõşÆΛƘǦöä ÆΛøʐŸõşøÆÆȽ ȘÀǵ Æƶ ¦**Storage** ȡΛÂǺϘöä

ƙÊõşÆΛƘǦöä ÆΛøʐŸõşøÆÆȽ ōøÆϘΛ ÛǒʐȒöä ǟÅÆȡ Ž ʔøϘǵ ¦**Additional information** ǦÆʐÅȓÜ ğÅɳʐŸȞɳ
.ʔŸʒɉä ģøäÀΣä ğÅǄøǻ Ž ȶÀèÜ ŌÒÀϘöä ȷʐÒΛ ÜɃʐƨä ƿÅΛȶä ǦæʐǜÀö ôÀȞϘöä ÆΛʒ ÅÆƶøÆǨ

REQUIREMENTS ƘǦǚÏƱƘǆ!ƒ

ɍş %98.5 ȡʒ ŌŌΛ ɍ Åɳ ʔŸʒ ƙÊõşÆΛƘǦöä ÆΛøʐŸõşøÆÆȽ Ƀʐϙʒ ¦**General requirement** ȳÅȞöä ÆŸÛϘȶä
.ǦÀÀǑä ģǻÅȶä ɃÜ ȶʐǄÀöÅæ ǦæʐÊȚ Û$C_8H_{11}NO_3,HCl$ ȡɳ %101.0 ȡʒ ÆΛÂΛ

:**Identity tests** ƕĭŇǌNJǁǁ ǀ ƐƥƑƑǂƢƐ

0.1) ÕƛǿǭŸõşǿǼŦTā Ȍ ƥ ȯǭŸŢ Ž Ōŋ/ȳāȂɖşȂȮŋ 10 ÂŦõȂǪǣ ȯǭŸǂ ȋ ȦÔǪŋŗā ǬĿù ǼŁȦȊƚ ȦŋǼȦʒ :A 290 ǦǣǟȂȩ ǦDZǬŋ ȯǭù Ž ǞŁȶŢʒǕ ǞȍȦÔǪŋā ɃǼǦ ¢ǫǔǭ ǕȂǪŋǬǫȦǫ 350ş ȂǪŋǬǫȦǫ 230 ƙǣ ǯāǬŋǕ ȯāǭùǕ Ž ǕVS (ȯ/ȯǭŋ âȦŦŐŸŏ ǈè 2 ȄŦŐǩ ğāƘDzǵ ȯȦȶȞǪèā ŌȒȦȦ) 0.43 ǦǣǟȂȩ āǾŁ ǦDZǬţā ȯǭù Ž ǈè 1 ǦǫȦǺǯǣ ǦŐǦùǕ ȋ ȦǪ ŋŸǦ ǕȂǪŋǬǫȦǫ .(ǈè1 ǦǫȦǺǯǣ ǦŐǦǕŏ ȋ ȦȶǪŏā ǼÊƕƚş

Ȧŋ ǼŁȦȊȦ ȦŋǼȦʒ ǕTS Ǖ6.9 ŏȦŁȦǣ ğāǣ ğȦȦÊȦŏā Ǧəǿāǻ Ž Ōŋ/ŋŸŋ 0.5 ÂŦõȂǪǣ ȯǭŸǂ ȋ ȦÔǪŋŗā ǬĿù ɃǼǦ :B ǕȂǪŋǬǫȦǫ 324ş ȂǪŋǬǫȦǫ 254 ǦǣǟȂȩ ƙǪDZǬţā ƃǭù Ž ǞŁȶŢʒǕ ǞȍȦÔǪŋā ǕȂǪŋǬǫȦǫ 350ş ȂǪŋǬǫȦǫ 230 ǯāǬŋɉā ȯāǭùǕ ƙǣ ȯȦȶȞǪèā ŌȒȦȦ) ǼŦǨȦǪŏā ʔŸʒ Ǖ0.35ş 0.18 ǦǣǟȂȩ ǦŁȶŢʒɉā ǯāǬŋɉā ȯāǭùǕ Ž ǈè 1 ǦǫȦǺǯǣ ǦŐǦǕŏ ȋ ȦȶǪŏā ŋŸǦ .ǈè 1 ǦǫȦǺǯǣ ğȦŐǦǕŏ ȋ ȦȶǪŏā ǼÊʓş âȦŦŐŸŏ ǈè 2 ȄŦŐǩ ğāƘDzǵ

ğȦǪŦèǕ ȯǭŸŢ ȡŋ Ōŋ 2ş Ōŋ/ŋŸŋ 0.1 ÂŦõȂǪǣ ȯǭŸŢ ȡŋ Ōŋ 1 ǿāǼŌŋ Bş A ǿȦǦǪȵā ɄǿǣǬǦǕ Ž ʒȓǬȦ :C ȡŋ Ōŋ 1 ǿāǼŌŋ B āǬǦǫɉā ƃǕş ŏȦţā ȡŋ Ōŋ 1 ǿāǼŌŋ A āǬǦǫɉā ƃǕ ȣȦȒȦ .TS (ȯ/ȟ 150) ÂŦõȂǪǣ ȳǬȦǻǬÔŏā Ǧʒ ȂÊǣ ȣȦȒȦş °ȳ20 ǦǣǟȂȩ ǥǿāȂǵ ǦDZǿǻ Ž ɈȦǣǬǦǫɉā ɎõǻɆƚ .ǯȦǭş TS (ȯ/ȟ 50) ÂŦõȂǪǣ ÕƛǿǬǦŏā Ȍ ƥ ȯǭŸŢ ǕA āǬǦǫɉā Ž ȧǿȁǕ ɈǬŏ ǰǪȦȦ ǕTSȯǬǫȦǯȦǕ /ɈǬŦõşǿǭŸõ ɄəȦȦǪ -6 Ǖ2 ǼŦƍǿǭŸõ ȯǭŸŢ ȡŋ Ōŋ 1 āǬǦǫǕ Ōõ ƃǕ .B āǬǦǫɉā Ž ȧǿȁǕ ɈǬŏ ǼŁȦȊȦ ɍ ȦȶŦǣ

ǦŋȦȞŏā ȣāȞǪèɍā ğāǿȦǦǪȵā" ɈāǬȦʒ ǨƠ ȣǬȍǬţā B ŌʒȦȦǪŏā Ōŋ/ȟ 0.05 ÂŦõȂǪǣ ȯǭŸŢ ɄÛȞȦ :D .(121 ǦƕȦÔŏā Ǖ1 ǼŸŐā) ğāǼƛǿǭŸȮŸŏ ÂƀȶƓ ŌʒȦȦǪõ "General identification tests

ǨƠ ȣǬȍǬŋ ǬĿ Ȧȶõ ǿȦǦǪȵŗā ȯǭŸŢ ƘȒƠ ŌDZɉ ȟ 0.5 ŌȶȞǪÊȦ :**Heavy metals** ǦŸŦŐǯŏā (ğāÂŸȦŏā) ɈǻȦȞţā Ǖ(127 ǦƕȦÔŏā Ǖ1 ǼŸŐā) 3 ŏāȂDZɋā Ǖ"Limit test for heavy metals ǦŸŦŐǯŏā ɈǻȦȞţā ŌDZɉ ɃǼΣā ǿȦǦǪȵŗā" ɈāǬȦʒ .ȟ/ȳāȂɖşȂȮŋ 40 ȡʒ ǼȦÂȦ ɍ Ǖ(128 ǦƕȦÔŏā Ǖ1 ǼŸŐā) A ǦŐȦȦÛŏā ǼÊǵ ǦŸŦŐǯŏā ɈǻȦȞţā ʔǬǪŢ ƙȞƚ

ǞŁǬȦȍ ŏȦţā ȡŋ Ōŋ 10 Ž ȟ 0.50 ÂŦõȂǪǣ ȯǭŸŢ ɈǬȮȦ :**Clarity and colour of solution** ȯǭŸǂā ɈǬŏş ŏȦȦȍ .ɈǬŸŏā ȻǼʒş

.ȟ/ŋŸŋ 1.0 ȡʒ ǼȦÂȦ ɍ :**Sulfated ash** ǨȦŸÊţā ǻȦŋȂŏā

ɍ) ȒȦǺȦŋ Ǖ8ȓ ǨƠ ǦŦŐȦʒ ǥǿāȂǵ ǦDZǿǻ Ž ǨǣȦǯŏā ɈȂǬŏā ʔǿǪǵ ǬȦDzƚ :**Loss on drying** ǬŦȦDzǪŏȦǣ ǼŌȦŏā .ȟ/ŋŸŋ 5.0 ȡŋ ȂǯõǕ ǼŌȦȦ ɍ ǕR ȦȮŦŸÊŏā ǦŋɎŁ ǕǬȦDzƕ ȧǬǬ (Ɥǥəà ǈŸŋ 5 ǦǣǟȂȩ şǕ ȯȦȮèȦǣǬŸŦõ 0.6 ȡʒ ǼȦÂȦ

.3.5 – 2.3 ǕŌŋ/ŋŸŋ 10 ÂŦõȂǪǣ ȯǭŸŢ ŏȦŁȦǣ ŋŸǦ :**pH value** ŏȦŁȦǦŏā ǦȶŦȩ

ȣȦȒȦ ǕR1 ɄDzŸǯŏā ÕŦǪèɉā Ȍ ƥ ȡŋ Ōŋ 30 Ž ǕǦŦùǬǦȒŋ ǦǫşàǬŋ Ǖȟ 0.4 ǦǣǟȂȩ āāǾƚ :**Assay** ǦÊȦȦŌţā

VS (0.1) ... 10

(142 ... 1) A ... "Non-aqueous titration"

$C_8H_{11}NO_3,HCl$ ... 20.56 ... VS (0.1) ... 1

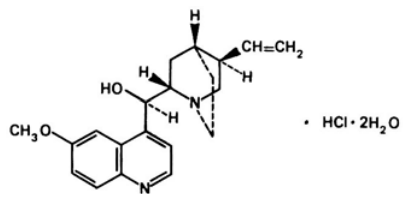
QUININI HYDROCHLORIDUM

Quinine hydrochloride

$C_{20}H_{24}N_2O_2,HCl,2H_2O$:**Molecular formula**

396.9 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

(8α,9*R*)-6′-Methoxycinchonan-9-ol monohydrochloride (salt) dihydrate; (8α,9*R*)-9-hydroxy-6′-methoxycinchonan hydrochloride (1:1) (salt) dihydrate; CAS Reg. No. 6119-47-7.

:**Description**

.R ... (~750) ... :**Solubility**

:**Category**

:**Storage**

:**Additional information**

R ...

REQUIREMENTS

... %98.5 ... :**General requirement**

.ǦÀÀÕă gẩÀţă Ƃǚ ţζDZÀǒÀǣş Û$C_{20}H_{24}N_2O_2,HCl$ ÀŒǚ ɁǛ3 ǦǣζÊƮ ǦĚǛÓǒă ğÀĽǭăζǛÕǒă ȡȠ %101.0

:**Identity tests** ǶǐǸǋǇǁ ǀ ƐƥƑǴǪǁ

ǒÀţÀǣ ȯζǛǂă ǻØĿ ȡȠ ÕȠ 0.5 ȤÀÁł .ǞÕǒǖǬȠ ȯζǛǂă ȷζÒǍ Ƒ ÜǒÀţă ȡȠ ÕȠ 2.5 ǿǻǢÕȠ Ž ȟ 0.1 ā ǻØǍ :A

.Ƀζę ȧǿǻǚ Ęǒǖǩ ǰǬǍǍ ÜTS(ȯ/ȟ100~) ÕǍǿζÀǛÊǒă Ȑ ƥ ȡȠ ȷÀǩÀÛę 8ÀȒǍş ÕȠ 100 ƪDZǕ ȯζǛƮ ɁǛ3 ȯζÔǶǛǒ

ȯζǛƮ ȡȠ ğǻÀÛę 5ş TS1 ÿşƎǒă ȯζǛƮ ȡȠ ğǻÀÛę 3-2 ÕȠ/ȠǛȠ 1 ÂĽÕÀǬǣ ȯζǛƮ ȡȠ ÕȠ 5 ǿǻǢÕȠ Ƃǚ 8ÀȒł :B

.ȸẩÀȠă ÀȒǹǚ ȷζǒ ǰǬǍǍ ÜTS(ȯ/ȟ100~) ÂĽÕÀǬǣ ÀĽǭζȠɉă

General ǦȠÀȞǒă 8ǻÀȞǬèɍă ğǻǿÀǦǬǹă" ȷǻζǍ3 ǨƠ 8ζòζţă B Õ3ÀÀǬǒă ÕȠ/ȠǛȠ 10 ÂĽÕÀǬǣ ȯζǛƮ ɄÛȞǍ :C

.(121 ǦǶÀÔǒă Û1 ǢǛÕă) ğǻǢǍǿζǛÒǛǒ ÂƀŧȠ Õ3ÀÀǬÕ "identification test

Ȑ ƥ ȯζǛƮ Ž ÕȠ/ȠǛȠ 20 ÂĽÕÀǬǣ ȯζǛƮ ÕŧȞǬÊǍ :**Specific optical rotation** Ʉ3ζÀǒă ȸÀÔǦǒă ÀǍşǢǬǒă

.$[\alpha]_D^{20°C}$ - 240 to - 258° ÜǦÀÀÕă gẩÀţă Ƃǚ ţζDZÀǒÀǣ ǢÊƷş VS(ȯ/ȯζȠ 0.1) ÕǍǿζǛÕşǿǢĽTă

ÕǍǿζÀǛÊǒă Ȑ ƥ ȯζǛƮ ȡȠ ÕȠ 1 ǿǻǢÕȠ ÕȠ/ȟ 0.3 ÂĽÕÀǬǣ ȯζǛƮ ȡȠ ÕȠ 15 Ƃǚ 8ÀȒł :**Barium** ÿζǍǿÀǦǒă

.ǦÕĽęẩ 15 ȡ3 ÕÕǩ Ƒ gǢȠ ǞĽζÀò ȯζǛǂă ɁÕǦǍ ÜTS (ȯ/ȟ 100~)

ǿÀǦǬǹɍă" ȷǻζǍ3 ǨƠ 8ζòζȠ ζĿ ÀŧÕ ÕŧȞǒă ÕŧÒłş ǒÀţă ȡȠ ÕȠ 20 Ž ȟ 0.5 ā ǻØł :**Sulfates** ğÀÀǛÊǒă

.ȟ/ȠǛȠ 1 ȡ3 ğÀÀǛÊǒă ɁζǬƮ ǢǍÂǍ Ƒ Ü(125 ǦǶÀÔǒă Û1 ǢǛÕă) "Limit test for sulfates ğÀÀǛÊǒă ÕDZɉ ȸǢΣă

ǞĽζÀò ǒÀţă ȡȠ ÕȠ 10 Ž ȟ 0.10 ÂĽÕÀǬǣ ȯζǛƮ ȷζÒǍ :**Clarity and colour of solution** ȯζǛǂă ȷζǒş ǒÀÀò

.ȷζǛǒă ǇǢ3ş

.ȟ/ȠǛȠ 1.0 ȡ3 ǢǍÂǍ Ƒ :**Sulfated ash** ǨÀǛÊţă ẩÀȠÀǒă

ȡ3 ÕÕǍ Ƒ ÀȠ ǢÕÀǍ Ü°ÿ 105 gǿǻÀǵ ǦDZǿẩ Ž ǨǣÀǯǒă ȷàζǒă ɁǿǬǵ ȤÀDZł :**Loss on drying** ȤĽÀDZǬǒÀǣ ǢÕÀǒă

.ȟ/ȠǛȠ 100 ȡ3 ǢǍÂǍ Ƒş ȟ/ȠǛȠ 60

ÛR ȷζǣÀÒǒă ǢĽÊÕǚ ɄǝÀǬ ȡȠ ƂÀƪă ǒÀţă Ž ÕȠ/ȠǛȠ 10 ÂĽÕÀǬǣ ȯζǛƮ ǒÀĿÀǣ ȠǛǦǍ :**pH value** ǒÀĿÀǦǒă ǦŧĽę

.7.0-6.0

ȷǻζǍ3 ǨƠ 8ζòζȠ ζĿ ÀŧÕ ǿÀǦǬǹɍă ĘǦÛł :**Related cinchona alkaloids** ǦǒÀÎţă ÀĽÒǒă ğÀĽǭǻζǛę

R1 ÀÒĽǛÊǒă ǦȠƳĿ ȯÀŧȞǬèÀǣ Û(84 ǦǶÀÔǒă Û1 ǢǛÕă) "Thin-layer chromatography ǦÕĽęÀǒă ǦÕǦÛǒă āǻÀÎǬèă"

ǿζÛÕ R ƘȠƳĽǯǚ ɄǝÀǬ ȡȠ ÿζDZǵ 5ş ÛR ƘǬɉă ȡȠ ǞŧDZǵ12 ÛR ȡǍζǒζǬǒă ȡȠ ǞŧDZǵ 20 ȡȠ ǰǍÂȠş ǦǛ8Ƞ gẩÀŧÕ

ȡȠ ȠǛȠ 10 Ƀζ3 :(A) ȯζǛǂă ÛR ȯζǭÀǯţă Ž ƘǍǭă ƘǒζǛƮ ȡȠ ÀǬǒşÀÒȠ 4 ǦǶÀÔǒă ɁǛ3 ǞƳÔÀÀȠ ĘǦÛǍ .ÕÀǶǬȠ

ȡȠ ǦǶÀÔǒă ţÂǭ ǢȞǣ .ÕȠ 1 ÕÕ Ž R ȡǍǢĽǭζÒÀĽÊǒă ȡȠ ȠǛȠ 0.25 Ƀζ3 :(B) ȯζǛǂăş ÕȠ 1 ÕÕ Ž ǿÀǦǬǹɍă gẩÀȠ

ÿζſèÌǩζǤöä ğÌÄÆƘŸæşåζΛ ȯζŸΗυŋ æÀǩ ÛåƎǬö ÕÀǬǩ ÜǦÕſęå 30 gÆŋ °ÿ105 gǿäÀǵ ǦDZǿå Ž ȸÁÊǩ Û ā äÀ ÎǬè ɍä gKDzǵ ȸŋ gÆì ÀǯÕÜ ÛǦſÊſəÀöä ǦȞÕǤöä ŏÀÀǯǬèÌæ ÛA ȯζŸǂä ȸŋ ǰǬÀǩ ǦȞÕæ ǦÀÜ ɉζÒǩ ɍ .ǿÀȚÀöä öζȑ Ž ǦΗſÀÔöä ÒΗÀǩş ÜTS .B ȯζŸǂä ȸŋ ǰǬÀǩ ƱøǬöä ÕŸǩ

ÛöÀţä ȸŋ Õŋ 20 Ž ÛǦſüζǤȒŋ Ǧφşäζŋ Ûȟ 0.2 ǦææÀę ā äǾƚ ؛**Limit of dihydroquinine** ƙÆſÕşǿÆſȽ ƱəÀǬ Æǵ ȸŋ Õŋ 0.1ş TS (ȯ/ȟ 70) ÕΛǿζŸÕşǿÆſTä ȒƥȯζŸȚ ȸŋ Õŋ 15 ÛR ÿζſèÌǩζǤöä ÆſŋşÀæ ȸŋ ȟ 0.5 8ÀȒΛ .ÀÀȍÜ ɉζö ǰǬÀΛ ƨøǬǵ VS (ȯ/ȯζŋ 0.0167) ÿζſèÌǩζǤöä ğÀŋşÀæ ȯζŸΗυŋ ÀΛÀȞΛ .TS ȯζφÀǯΛÜ/ ÕſǯſţägÀƥ ȯζŸȚ .ĘəÀęå 5 gÆŋ ÿŸȚöä Ž ǿäÀÕǬèŸö ÕÀǬǩş ÛǦŸDZζΣä ÆÊǩ ÛöÀţä ȸŋ Õŋ 200 Ž R ÿζſèÌǩζǤöä ÆΛåζΛ ȸŋ ȟ 0.5 8ÀȒƚ ǦζÀȑÜ ȝŋ ÛVS (ȯ/ȯζŋ 0.1) ÿζΛåζÔöä ğÀÄŸèζſǬ ȯζŸΗυŋ ȯζŸǂä Ž ÿζſèÌǩζǤöä ğÀŋşÀæ gåÀΛä ȸŋ ǿÀΗυǬţä åζſöä ÀΛÀȞƚ ÀſÕÀǬæ ÿζſèÌǩζǤöä ğÀŋşÀæ ȯζŸȚ ȸŋ Õŋ 1 Õõ .ǴǩÀÀöä ÀÀȍǰä БÜ ȯζŸǂä ɉζö ÕÔΛ ÀŋÆÀȝ TS ÀÎÀöä ȯζŸȚ ȸŋ Õŋ 2 ǦÊΛÀÕţä Žş ƙſȞǬöä äǾȽ Ž ƙǬDzſǬÀöä ȸȝ ƎȞƚ .$C_{20}H_{24}N_2O_2,HCl$ ȸŋ ŋŸŋ 18.04 ùζÀÒΛ VS (ȯ/ȯζŋ 0.0167) .%10 ȸȝ ƙǬÀǬɍä ƙæ ȧÀÀöä ÆΛÂΛ ɍ .ǦÀÀÒä gåÀţä БÜ ţζDZÀöÀæ ƙǬæζÊȚ ÛƙǬÕæζţä ƙǬΛζÀţä ƙǬǦÊÀöÀæ

8ÀȒΛ ÛR1 ƱDzŸǯöä ÕſǬſèǰä ȒƥȸŋÕŋ 50 Ž ÛǦſüζǤȒŋ Ǧφşäζŋ Ûȟ 0.35 ǦææÀę ā äǾƚ ؛**Assay** ǦÊΛÀÕţä ÕΛǿζŸÕƘǤöä ȒŧШ ÀΛÀȞΛş ÛTS ÕſǬſèǰä Ȓƥ /ĘǤəÂöä ğÀǬſèÜ ȯζŸȚ ȸŋ Õŋ 10ş R ÕſǬſèǰä ÆΛǿÆſŒÜ ȸŋ Õŋ20 A ǦÕΛÀÛöä "Non-aqueous titration ƱəÀŋŸöä Ùèζöä Ž gÀΛÀȞţä" ɉæζΛȝ ǨƠ 8ζȍζŋ ζȽ ÀŧÕ VS (ȯ/ȯζŋ 0.1) ȸŋ ŋŸŋ18.04 ùζÀÒΛ VS (ȯ/ȯζŋ 0.1) ÕΛǿζŸÕƘǤöä Ȓƥ ȯζŸȚ ȸŋ Õŋ 1 Õõ .(142 ǦΗÀÔöä Û1 ÆŸÕä) .$C_{20}H_{24}N_2O_2,HCl$

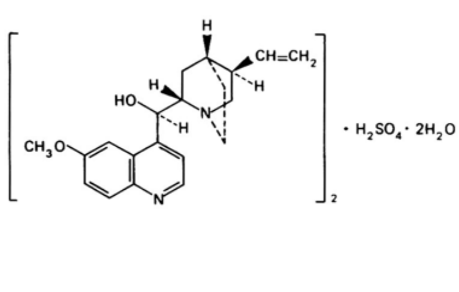
QUININI SULFAS

Quinine sulfate DZǐǅǐǀǁƐ ǀƑǂƨ

$(C_{20}H_{24}N_2O_2)_2,H_2SO_4,2H_2O$ ؛**Molecular formula** ǦƂÀΛÂƨä Ǧ8ſÔöä

783.0 ؛**Relative molecular mass** ǦǤÊÀöä ǦƂÀΛÂƨä ǦŸǬÒöä

؛**Graphic formula** ǦƃφÀƸǤţä Ǧ8ſÔöä



[illegible] **Chemical name**:

(8α,9*R*)-6′-Methoxycinchonan-9-ol sulfate (2:1) (salt) dihydrate; (8α,9*R*)-9-hydroxy-6′-methoxycinchonan sulfate (2:1) (salt) dihydrate; CAS Reg. No. 6591-63-5.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] (~750 [illegible]) [illegible] R.

[illegible] **Category**: [illegible].

[illegible] **Storage**: [illegible].

[illegible] **Additional information**: [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 99.0% [illegible] 101.0% [illegible] $(C_{20}H_{24}N_2O_2)_2,H_2SO_4$ [illegible].

[illegible] **Identity tests**:

A: [illegible] 5 [illegible] 10 [illegible] (~100 [illegible]) [illegible].

B: [illegible] 5 [illegible] 1 [illegible] TS1 [illegible] 5 [illegible] (~100 [illegible]) [illegible].

C: [illegible] 20 [illegible] A [illegible] "General identification tests" [illegible] (123 [illegible] 1 [illegible]).

[illegible] **Specific optical rotation**: [illegible] 30 [illegible] (~100 [illegible]) TS [illegible] $[\alpha]_D^{20°C}$ = -240 to - 250° [illegible].

[illegible] **Clarity and colour of solution**: [illegible] 20 [illegible] 5 [illegible] (0.1 [illegible]) VS [illegible] 10 [illegible] Yw2 [illegible] "Colour of liquids" [illegible] (53 [illegible] 1 [illegible]).

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible].

ȡŋ ȀǯŏǕ ǼŎȀȂ ɍ Ǖ°ÿ105 ǥǿǟȀǵ ǦǱǿǻ Ž ǨǟȀǯǟǟ ȷàȥǟǟ ʔøǪǵ ȤȀǱǲ :**Loss on drying** ȤǾȀǱǪǾȀǟ ǼŎȀǟǟ .ȟ/ŋŸŋ50

-5.7 ÛR ȷȥǟȀȮǟǟ ǼǾÊŏǕ ɄǝȀȀǫ ȡŋ БȀʅǟ ǒȀţǟ Ž Ōŋ/ŋŸŋ 10 ÂǾŎȀǪǟ ĘŸȞǪÊŋ ǒȀȽȀǟ ŋŸǤȀ :**pH value** ǒȀȽȀǤǟǟ ǦȶǾȩ .6.6

ȷǟȥȀȝ ǨƠ Ȣȥòȥŋ ȥȽ Ȁȶŏ ǿȀǤǪǹɍǟ ĘǤÛǲ :**Related cinchona alkaloids** ǦǒȀÎţǟ ȀǾȮǟǟ ǧȀǾǫǟȥŸȩ R1 ȀȮǾŸǾÊǟǟ ǦŋŸȽ ǒȀȶȞǪèȀǟ Û(84 ǦȞȀÔǟǟ Û1ǼŸǑǟ) "Thin-layer chromatography ǦŎǾȩȀǟǟ ǦŎǤÛǟǟ āǟȀÎǪèǟ" ǿȥÛŏ R ȸŋŸǯǕ ɄǝȀȀǫ ȡŋ ÿȥǱǵ 5ȿ ÛR ǨǪɉǟ ȡŋ ȀȶǱǵ 12 ÛR ȡȀȥǒȥǪǟǟ ȡŋ ȀȶǱǵ 20 ȡŋ ǰȀÂŋȿ ǦŸǯȢŋ ǥǟȀȶŏ ȡŋ ŋŸŋ 10 ɃȥȜ :(A) ȯȥŸɉǟ ÛR ȯȥǫȀǯǾţǟ Ž ȸȀǪǟ ȸȯȥŸȚ ȡŋ ȀǪǒȿȀȮŋ 4 ǦȞȀÔǟǟ ʔŸȝ ȸŸÔȀȀŋ ĘǤÛǲ .ŏȀȞǪŋ ȡŋ ǦȞȀÔǟǟ ţȀǫ ǼȞǟ .Ōŋ 1 Ŏŏ Ž R ȡȀǼǾǫȥȮȀǾÊǟǟ ȡŋ ŋŸŋ 0.25 ɃȥȜ :(B) ȯȥŸɉǟȿ Ōŋ 1 Ŏŏ Ž ǿȀǤǪǹɍǟ ǥǟȀŋ ÿȥǾèȀǩȥǤǟǟ ǧȀǾǩŸǟȿǻȥȀ ȯȥŸȞŋ ǽȀǩ ÛǻȜǪǒ ŏȀǪǩ ÛǦŎǾȩǻ 30 ǥǼŋ °ÿ105 ǥǿǟȀǵ ǦǱǿǻ Ž ȡǺÊǩ Ûāǟ ȀÎǪèɍǟ ǥǨǱǵ ȀǯŏǕ ÛǦǾÊǾǝȀǟǟ ǦȞŎǤǟǟ ǒȀǯǪèȀǟ ÛA ȯȥŸɉǟ ȡŋ ǰǪǩ ǦȞŎǟ ǦȀǕ ȷȥȮǩ ɍ .ǿȀȚȀǟǟ ǒȥȑ Ž āǟȀÎǪèɍǟ ǙÛƯ ȎȞȀȿ TS .B ȯȥŸɉǟ ȡŋ ǰǪǩ ɄøǪǟǟ ŎŸǩ ȡŋ ǥǼȉ

.ǒȀţǟ ȡŋ Ōŋ 20 Ž ÛǦǾùȥǤȒŋ ǦǫȿàȥŋÛȟ 0.2 Ǧǟǟȩ āǟǾ :**Limit of dihydroquinine** ȸǼŏȿǿǼǾȽ ɄǝȀȀǫ Ǽǵ ǥȀƥ ȯȥŸȚ ȡŋ Ōŋ 0.1ȿ TS (ǒ/ȟ 70~) ŎȀǿȥŸŏȿǿǼǾȚǟ Ȓƥ ȡŋ Ōŋ 15 ÛÿȥǾèȀǩȥǤǟǟ ǼǾŋȿȀǟ ȡŋ ȟ 0.5 ȢȀȒȀ ȟ 0.5 ȢȀȒȀ .ȀȀȍǕ ȷȥǒ ǰǪȀ ʔøǪǵ VS(ǒ/ǒȥŋ 0.0167) ÿȥǾèȀǩȥǤǟǟ ǧȀŋȿȀǟ ȯȥŸȞŋ ȀȀȞǲ .TS ȯȥǫȀǯȀǕ/ŎǾǯǾţǟ ǻȥǾǟǟ ȀȀȞȀ .ĘȀȩǻ 5 ǥǼŋ ÿŸȚǟǟ Ž ǿǟȀŎǪèŸǒ ŏȀǪǩȿ ǦŸǱȥȜǟ ǼÊǩ ÛǒȀţǟ ȡŋ Ōŋ 200 Ž R ÿȥǾèȀǩȥǤǟǟ ǼȀǻȥȀ ȡŋ ȡŋ Ōŋ 2 ǦȥȀȑǕ ȝŋ ÛVS(ǒ/ǒȥŋ 0.1) ÿȥȀǻȥÔǟǟ ǧȀȀŸèȥǾǫ ȯȥŸȞŋ ȯȥŸɉǟ Ž ÿȥǾèȀǩȥǤǟǟ ǧȀŋȿȀǟ ǥǟȀȀà ȡŋ ǿȀȞǪţǟ 0.0167) ÂǾŎȀǪǟ ÿȥǾèȀǩȥǤǟǟ ǧȀŋȿȀǟ ȯȥŸȚ ȡŋ Ōŋ 1 Ŏŏ .ǴǨȀȀǟǟ ȀȀȍɉǟ БǕ ȯȥŸɉǟ ȷȥǒ ǑÔȀ ȀŋǼȀȝ TS ȀÎȀǟǟ ȯȥŸȚ ȸǪǤÊȀǟȀǟ ǦÊȀȀŎţǟ Žȿ ȸǾȞǪǟǟ ǟǾȽ Ž ȸǪǱǾǪȀǟǟ ȡȝ ȜȞȀ .$(C_{20}H_{24}N_2O_2)_2,H_2SO_4$ ȡŋ ŋŸŋ 24.90 ùȥȀȮȀ VS (ǒ/ǒȥŋ .%10 ȡȝ ȸǪǪɍǟ ȸǟ ǟȀȀǟǟ ǼȀÂȀ ɍ .ǦȀȀǑǟ ǥǟȀţǟ БǕ ţȥǱȀȀǟȀǟ ȸǪǟȥÊȚ ÛȸǪŏȥǟȥţǟ ȸǪȀȥȀţǟ

ȢȀȒȀ ÛR1 ɄǱȥŸǯǟǟ ŎǾǪǾèɉǟ Ȓƥ ȡŋ Ōŋ 30 Ž ÛǦǾùȥǤȒŋ ǦǫȿàȥŋÛȟ 0.20 Ǧǟǟȩ āǟǾ :**Assay** ǦÊȀȀŎţǟ ǨƠ Ȣȥòȥŋ ȥȽ Ȁȶŏ VS (ǒ/ǒȥŋ 0.1) ŎȀǿȥŸŏǨǤǟǟ ȒȶȀ ȀȀȞȀȿ ÛR ŎǾǪǾèɉǟ (ɄǝȀŋŸǟǟ) ǼȀǿǼǾǼǟ ȡŋ Ōŋ20 ȡŋ Ōŋ 1 Ŏŏ .(142 ǦȞȀÔǟǟ Û1ǼŸǑǟ) A ǦŎȀȀÛǟǟ Û"Non-aqueous titration ɄǝȀŋŸǟǟ Ȕèȥǟǟ Ž ǥȀȀȞţǟ" ȷǟȥȀȝ .$(C_{20}H_{24}N_2O_2)_2,H_2SO_4$ ȡŋ ŋŸŋ 24.90 ùȥȀȮȀ VS(ǒ/ǒȥŋ 0.1) ŎȀǿȥŸŏǨǤǟǟ Ȓƥ

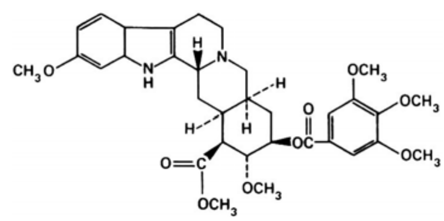
RESERPINUM

Reserpine ƊžĩǴƥĩŘĩƥǁ

$C_{33}H_{40}N_{2}O_{9}$ ¦**Molecular formula** ǦƦǺǺƨǡ Ǧ8ƗÔǟ

608.7 ¦**Relative molecular mass** ǦƗǴÊǺǟ ǦƦǺǺƨǡ ǦŸǪȮǟ

¦**Graphic formula** ǦǶǺƗǴǭǟ Ǧ8ƗÔǟ



¦**Chemical name** ȹǝǺƗȶƗȮǟ ȴèɍǟ

Methyl 18β-hydroxy-11,17α-dimethoxy-3β,20α-yohimban-16β-carboxylate 3,4,5-trimethoxybenzoate (ester); methyl 11,17α-dimethoxy-18β-[(3,4,5-trimethoxybenzoyl)oxy]-3β,20α-yohimban-16β-carboxylate; CAS Reg. No. 50-55-5.

ǰƗǴǟ БǕ ȐƗǕ Ƀǿƺǣ ȧƺǶÊƞ ȿǕ ÛƘȽǺǴǟ ǰƗǴǟ БǕ ȐƗǕ ɉƺǐ ǧǟǣ ǥƘ8ò ǧǟǿƺǣ ¦**Description** Ƶòƙǟ .ǦǶǝǺǟ ƇƐȝ ÜƘȽǺǴǟ

ȡƞ ǒǟÂǄǕ 6 Žȿ R ɉƺǬèɉǟ ȡƞ ǟǒÂǄ 90 Ž ǡǟȿǣ ÜǒǺȶǟ Ž ǟƗŸȶȝ ǡǟȿǣ ƘȡǱ ¦**Solubility** ǦƗǶǺǣȿǾǟ .R ƘǬɉǟȿ ÛTS (ȯ/ȟ750~) ȯƺǶǺǮǪǟ ÛR ȯƺǶǺǮƗȶǟ Ž ǟǺƐǄ ɉǺǣȿǾǟ ǴƗǶȉ ÜR ȳǿƺƺȿǿƺŸȮǟ

.ȳƐǟ Ȕ8Ȓǐ Ȑƺǡǹ ÛɉǺȽǾǟ ǻǺȒƞ ¦**Category** ǦǺǼǟ

.ǒƺȒǟ ȡƞ ǦƗȶȚ ÛƗƐƗǄ ǦǑŸ8ƞ ǦǺȿǺǵ Ž ƘǣȀǺǺÀǺǟ ȘǺǵ Ǣƶ ¦**Storage** ȡǺÂǺǪǟ

ȡȮǒȿ Ûǒƺ ȒŸǒ ôȀǞǪǟ ƐǺȝ ǒȔǴǣ ǺǺõǟǻ ƘǣȀǺǺÀǺǟ ɉƺǐ ǴǴÔǺ ¦**Additional information** ǦƗƺǺȑǕ ǧǺƞƺŸȟƞ .ȯƺŸɉǟ Ž ȜõǕ ǴȝȀÊǣ

REQUIREMENTS ƘǴǕǭƙǆ!ƒ

ȡƞ %102.0 ȡȝ ƐǺÂǺ ɍȿ %98.0 ȡȝ ÕǑǺ ɍ Ǻƞ ȝŸȝ ƘǣȀǺǺÀǺǟ Ƀƺǫȝ ¦**General requirement** ȳǺȞǟ ƆŸÛǪȶǟ

.ǦÀÀÕä gẩÀƫä Бǚ ƫ ɀ ǅZÀ̀ÕÀ̇æ Ǧæ ɀ Ê Ƭ Û $C_{33}H_{40}N_2O_9$

:**Identity tests** ƕïŇǰŇǁɛ Ɩ ɛƥƑǶǖǀɛ

• ȡǑƹ ǘ Û ƗƐ ÀƏ ɸ Ȃ ǺÀ ɳ A ÀÀ ʂɑ Ǻ ȿ Ǜ ɲ ȡ ǖ Ȃ ɸ ǼC ƹ.

ɑÀ ɸ ȡǖ ǑÀ ǚ :A Ǔ ɔ ȡȝ ȫ ǔ ǃ ʘ ɳ Ǆ ɮ Ǆǚ ȿ "Ǆǚ ǚ ɢ Ɉ Ȍ ɔ ǅ ɬ ǚ Ǘ ǃ ɐ ɔ ǁ Ǡ ɲ ƸÀ Ž ǣ ǽ ɛ ĕ Ǌ Ǵ ǎ Ȍǆ ȳ ǅÀ Ʊ

Ǒ Ǵ ǎ Ǩ Ž ĩ ǹȮ ɬ ɸ ȿȂ Ǚ ɂÀÛ ǀ .(43 ǦǶÀÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region

.ƙæÀ̀ÀÂÀ̀Ÿö *reflected spectrum* ɄȞǅÀ ƫ ä ȤǅÛöä ȝ ɳ ȿ ǚ RS ƙæÀ̀ÀÂÀ̀öä ȡ ɳ ǰ ȹ ɃǾöä Ȥ ǅÛöä ȝ ɳ ɑ ȕ ǣ

Ȑ ƥ Ž ÀDZàÀ̇ù ÀȒ ǂ ä R ƙ ŸƐ ÀÀöä ȡ ɳ ȯ/ȟ 10 ÂƐõÀ̀ǅæ ȯȤ ŸƬ ȡ ɳ Ǒ ɳ 0.2 ǿäÆŌ ɳ ɳŸɳ1 Бǚ Ȣ ÀȒ :B

.ƙǅǑǅǝ ȯ Ÿǹ (ɄŸÀǅÀȩ À̀ƥǚ) Ƀǻ ȿ ȿ ǰ ȿ ǰ ǅÀ ÜTS(ȯ/ȟ 205~) ȬǅȿȤŸȭȿÆɛTä

R ɄDZŸǯöä ȬǅǅȨ ǂ ä Ȑ ƥ ȡ ɳ Ǒ ɳ 0.2ȿ R ÆƐȽÆöäÂ ø Àæ ȤÆɳǚ ǑƐǯƐ ɳ ɄəÀÀȩ -4 ȡ ɳ ɳŸɳ 5 ȝ ɳ ɳŸɳ 0.5 ǯÂ ɛ :C

ȬǅǅȨ ǂ ä Ȑ ƥ ȡ ɳ Ǒ ɳ 1 Ȣ ÀȒÀ .ÀȒǹǚ ɉ ȿ ǰ ǅÀ ÜTS (ȯ/ȟ1760~) ȬǅȿȤÀŸÊöä Ȑ ƥ ȡ ɳ Ǒ ɳ 0.2 Ȣ ÀȒɬȿ

.Àƥ ǂ ä Бǚ ɉ ȤŸöä ȯ ȤǶǅÀ ÜR ɄDZŸǯöä

ÜR ȳȿ ȤȤȿȿ ȤŸȮöä Ž Ǒ ɳ/ɳŸɳ 10 ÂƐõÀ̀ǅæ ȯȤ ŸƬ Ǒ ƫ ȞǅÊÀ :**Specific optical rotation** Ʉȝ ȤÀöä ɃÀ̀ÔǦöä À̀ÀȿÆǅöä

.$[\alpha]_D^{20°C}$ -113 to -127°

.ȟ/ɳŸɳ 1.0 ȡȝ ÆÀÂÀ ɍ :**Sulfated ash** ǨÀŸÊƫä ǻ ÀɳÀ̀öä

ɍ) ȐÀǺ Àɳ Ǜ8 ȑ ǨǑ °ȳ60 gǿäÀ̀ǵ ǦDZǿǻ Ž ǨæÀǯöä ɉ àȤöä ʡ ȿ ǅǵ Ȥ ÀDZɬ :**Loss on drying** Ȥ ƐÀDZǅöÀæ ÆǑÀöä

.ȟ/ɳŸɳ 10 ȡ ɳ À̀ǯõǚ ÆǑÀÀ ɍ Ü(ǅǦəä Ɩ Ÿɳ 5 Ǧææ Àȩ ȿǚ ȯÀȮȨÀæ ȤŸƐõ 0.6 ȡȝ ÆÀÂÀ

Ž Ǒ ɳ/ɳŸɳ 0.2 ÂƐõÀ̀ǅæ ȯȤ Ÿ ǂ Ɩ ȍ 1 ǦȩÀǺǯæ ǦǑǦÛõ ĩ Àƫǅöä ȃÀǑɬ :**Oxidation products** gÆÊõ ǂ ä ǧ ÀDZȤǅÀɳ

ȯÀƫȞǅȍä ǑȒÀÀ) 0.10 ȡ ɳ Ǝõǚ ɉ ȤȮÀ ɍ ÜÀǅɳȤȩÀȩ 388 ǦææÀȩ ɄƫȚȝǚ ǦDZȤ ɳ ȯȤù Ž R ɄDZŸǯöä ȬǅǅȨ ǂ ä Ȑ ƥ

.(Ɩ ȍ 1 ǦȩÀǺǯæ ǦǑǦÛõ ĩ Àƫǅöä ÆÊȝ ȿ ȃÀƐǑŸö Ɩ ȍ 2 ȄƐǑǨ ǧäǨDZǵ

:**Assay** ǦÊÀÀǑƫä

• Æ ʑ ɉ ǚ ʡ ƫ ǑÀ ɍǅÀ ǂ ä ǑƐöÀ ǂ ä ȡ ɳ ǑäȤTä ǑäȒöä ȿ ȤȒöä ǑÀÀȩǚ .ǦÊÀÀǑƫä ÆùÀ̀ɬ Ǧææ Àȩ 25 ɳŸɳ Û ȤǅÀǅȤ ɳ Ǧȩȿ À̀ȤǦ ȒɳÛǦƐù ȝ ɳ 2 Ǒ ɳ ȡ ɳ

750~) ȯȤȩÀǯÀɋ ä ȡ ɳ Ǒ ɳ 10ȿ VS (ȯ/ȯȤ ɳ 0.25) ȬǅȿȤÀŸÊöä Ȑ ƥ ȡ ɳ Ǒ ɳ 2 Ȣ ÀȒɬ ÛTS (ȯ/ȟ750~) ȯȤȩÀǯÀɋ ä

5.0 Ȥ ÀǺɬȿ ÛTS (ȯ/ȟ 750~) ȯȤȩÀǯÀɋ Àæ Ǒ ɳ 100.0 ʡ ȿ ǅǵ Ȥ ÀǺɬ ÛǻƎɬ .ȯȤŸ ǂ ä ǑƐȞÀȩ Ȥ ÛŸæ ÜȤÆÀȿ ÛTS (ȯ/ȟ

ȡ ɳ Ǒ ɳ 2.0 Ȣ ÀȒÀ Ûɉ ÀƐŸȡ ǡ ȤǦȩǚ Бǚ ȯȤŸ ǂ ä ȡ ɳ Ǒ ɳ 10.0 ǑǑÀɬ .¢ÊÀȩ ÆÀǾƫÀæ Ǒ ɳ 50.0 Бǚ ȯȤŸ ǂ ä ǾȽ ȡ ɳ Ǒ ɳ

ÛȞǅDZàÀ̇ù ÀȒ ǂ ä TS (ȯ/ȟ 3) ÂƐõÀ̀ǅæ R ȳȤÀǻȤÔöä ǨÀÀ̀ǅȩ ȯȤ ŸƬ ȡ ɳ Ǒ ɳ 2.0ȿ VS(ȯ/ȯȤ ɳ 0.25) ȬǅȿȤÀŸÊöä Ȑ ƥ

[illegible] 1.0 [illegible] 30 [illegible] 55 [illegible] TS (750~) [illegible] 25.0 [illegible] TS (50) [illegible] 390 [illegible] 1 [illegible] 10.0 [illegible] RS [illegible] $C_{33}H_{40}N_2O_9$ [illegible] 2 [illegible] 0.01 ± 0.42 [illegible] 1 [illegible].

[illegible]

Additional requirements for Reserpine for parenteral use

.(36 [illegible] 4 [illegible]) "*parenteral preparations* [illegible]" [illegible]

[illegible] **Bacterial endotoxins** [illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible]" [illegible] RS [illegible] IU [illegible] 71.5 [illegible] 1 [illegible].

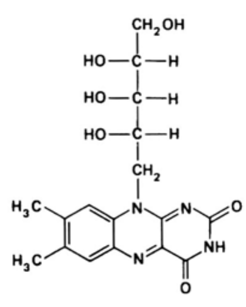
RIBOFLAVINUM

Riboflavin [illegible]

$C_{17}H_{20}N_4O_6$ **Molecular formula** [illegible]

376.4 **Relative molecular mass** [illegible]

Graphic formula [illegible]



Chemical name [illegible]

7.8-Dimethyl-10-(D-*ribo*-2,3,4,5-tetrahydroxypentyl)iso-
alloxazine; CAS Reg. No. 83-88-5.

[illegible] **Description**: [illegible]

[illegible] **Solubility**: [illegible] (1 in 750~) [illegible] TS [illegible]
[illegible] R [illegible] R [illegible]

[illegible] **Category**: [illegible]

[illegible] **Storage**: [illegible]

[illegible] **Additional information**: [illegible]
[illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 98.0% [illegible]
102.0% [illegible] $C_{17}H_{20}N_4O_6$ [illegible]

Identity tests: [illegible]

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 43 [illegible]). [illegible]
[illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 1 [illegible] 100 [illegible]
[illegible].

[illegible] **Sulfated ash**: [illegible] 3.0 [illegible].

[illegible] **Loss on drying**: [illegible] 105°[illegible] [illegible] 15 [illegible].

[illegible] **Lumiflavin**: [illegible] 25 [illegible] 10 [illegible] R [illegible] 5 [illegible]
[illegible] 1 [illegible] 440 [illegible]
[illegible] R [illegible] 0.025 [illegible] 2 [illegible]
[illegible] 1 [illegible]).

Assay: [illegible]

• Ǽƶ ǰ̈ ʔǼθ ǧǼŁǺǭ Ž ȑǭǿ Ǩǽǹ.

Ǻ8 ǺȒ Ɓǰ ǻǼǧ 0.075 ǰȓ Ǧǻǹ ǼǫȒǭ ǿǼ 5 ǻǹ ǿǺǧǾǼǻ ǼǼǿ ǰ ǻǼǿǾǽ ǿǻǽ ǰǼ ǿǹǿǿ ǿǺǺǻǼ ǵǧ ǼǽǭȒ ǼǼ ȑǿǽǼ.

8Ǻ Ǻ8 ǹ Ǽǿ 5 ǹ Ǽ ǿǻǭ ǼǹǿǼ ǿǻǽǼǼǧ ǿǼǼǹ (ȯ/ȟ80~) ȤȘ. ǹǽ ǰ ȧǽ ǿǭȘ ǫǼǹ ǫȒ ǼǼǿǼ.

ǺǾǻ Ǻ8 100 ǻǼ ǿǹ ǹ ǼǼ 2.5 ǻǼ ǿǹ ȝ Ȓ ǹǽǿ ǿ ǼǼǹǼǫ Ȓ ǿǼǹǼǿ ǿǼǹǻ ȸǼǿǭȝ ǿǺǿǼ ǿǽ ǼǼǿǽ ǿǹǿ ǫǽǹ

(ȯ/ȟ 50) ǼǼǿǼǽ ǻǾ ǿǼǹ ǿ ǻǼ 1 ǹǼ ǿǼǿǹ ǿǹ ǫǼ 10 Ɓǰ Ǻ8 .ǹǻ 1000 Ȼǿǹ

ȤȘ ǼǼǿ 8ǹ ǹǽ ǻǼǿ ǿǹǽ ǻǼ 50 Ȼǿǹ. ǼǼǫ ǿǹǼǿ ǿǼǹǼǹ ǫ 1 Ȼǹ ǹǽ ǿǹǿ ǭǼǿ Ƶ

Ž $C_{17}H_{20}N_4O_6$ ǹǽ ǿǼǹǿ ǿǹ Ǿǹ ǹǹ Ǧǻ 444 ǿǼǻǼ. ǼǧǼ ǹǼ ǹǿ ǭǹ Ǽǿǽ Ǿǹ ǭǹǹǽ

ǼRS ǿǹǿǽ ǹ ǿǼǹǽ ǹǽǼǿ.

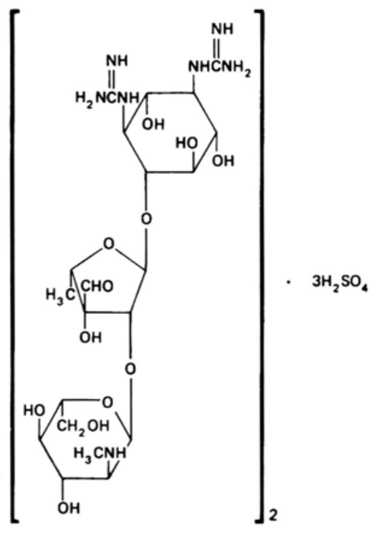
STREPTOMYCINI SULFAS

Streptomycin sulfate ǻǽǻ ǿǹ ǻǼǹǿ

$(C_{21}H_{39}N_7O_{12})_2,3H_2SO_4$:**Molecular formula** ǿǼǿǺǻ ǿǼǼǿ

1457 :**Relative molecular mass** ǿǼǿǼǹ ǿǼǿǺǻ ǿǹǿǹ

:**Graphic formula** ǿǼǿǼǿ ǿǼǼǿ



:**Chemical name** ǿǼǿǹǿ Ȼǹ

O-2-Deoxy-2-(methylamino)-α-L-glucopyranosyl-(1→2)-*O*-5-deoxy-3-*C*-formyl-α-L-lyxofuranosyl-(1→4)-*N*,*N*′-bis(aminoiminomethyl)-D-streptamine sulfate (2:3) (salt); CAS Reg. No. 3810-74-0.

[illegible] **Description** :[illegible]

[illegible] **Solubility** :[illegible] (~750) [illegible] R [illegible]

[illegible] **Category** :[illegible]

[illegible] **Storage** :[illegible] 30° [illegible]

[illegible] **Labelling** :[illegible]

[illegible] **Additional information** :[illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement** :[illegible] %90.0 [illegible] $(C_{21}H_{39}N_7O_{12})_2, 3H_2SO_4$ [illegible] 720 [illegible] 1 [illegible]

Identity tests [illegible]:

A: [illegible] 20 [illegible] 5 [illegible] 10 [illegible] (1 [illegible]) 3 [illegible] (~250 [illegible]) TS 1 [illegible] (25 [illegible]TS) [illegible]

B: [illegible] 0.1 [illegible] 2 [illegible] 1 [illegible] -1 [illegible] TS1 2 [illegible] (~40 [illegible]) TS [illegible]

C: [illegible] 20 [illegible] A [illegible] General "identification tests [illegible] (123 [illegible] 1 [illegible]).

[illegible] **Clarity and colour of solution** :[illegible] 1.0 [illegible] 10 [illegible] Yw4 [illegible]

.(53 [illegible]) "Colour of liquids

[illegible] 0.6 [illegible] ؛**Loss on drying** [illegible] 60° [illegible] 70 [illegible] 5 [illegible]

-4.5 [illegible] 0.25 [illegible] ؛**pH value** [illegible] 7.0.

0.05 [illegible] 5 [illegible] 0.2 [illegible] ؛**Methanol** [illegible] 2.5 [illegible] (0.05 [illegible]) [illegible] 10 [illegible] (0.0167 [illegible]) [illegible] 25 [illegible] 1 [illegible] 30 [illegible] (~1760 [illegible]) [illegible] 10 [illegible] (80 [illegible]) [illegible] 12.5 [illegible] 500 [illegible] (0.1 [illegible]) [illegible] 5 [illegible] (0.1 [illegible]) [illegible] 1 [illegible] (0.1 [illegible]) [illegible] 0.534 [illegible] CH_4O [illegible] 40 [illegible] CH_4O.

؛**Assay** [illegible]

[illegible] ؛**For streptomycin sulfate** [illegible] 0.10 [illegible] 5 [illegible] 5 [illegible] 100 [illegible] 3 [illegible] 5 [illegible] 10 [illegible] (0.2 [illegible]) [illegible] 25 [illegible] TS2 [illegible] 525 [illegible] 1 [illegible] TS2 [illegible] 20 [illegible] $(C_{21}H_{39}N_7O_{12})_2,3H_2SO_4$ [illegible] 1.18 [illegible] (11.8 $E^{1\%}_{1\,cm}$).

[illegible] ؛**For potency** [illegible] (a) [illegible] (155 [illegible]) "Microbiological assay of antibiotics [illegible] 7.9 [illegible] Cm 1 [illegible] (11774 ATCC [illegible] 8236 NCTC) *Bacillus subtilis*

[illegible] 20 [illegible] 5 [illegible] TS2 [illegible] TS1 [illegible] 8.0 [illegible] 8.0 – [illegible] (ATCC 6633) *Bacillus subtilis* [illegible] (b) [illegible] 39 – 36 [illegible] IU [illegible] TS2 [illegible] TS1 [illegible] 8.0 [illegible] 8.1 - 8.0 [illegible] Cm1 [illegible] .°37 – 35 [illegible] IU [illegible] 15 [illegible] 3 [illegible] %95 [illegible] (P = 0.95) [illegible] 720 [illegible] (P = 0.95) [illegible] %105 [illegible] 1 [illegible] IU [illegible].

[illegible]

Additional requirements for Sterile Streptomycin Sulfate

[illegible] :Histamine-like substances [illegible] 1 [illegible] (167 [illegible]) "Test for histamine-like substances [illegible] TS [illegible] 1 [illegible] 3 [illegible].

"Sterility testing of [illegible] :**Sterility** [illegible] (162 [illegible]) Antibiotics [illegible].

[illegible]

Additional requirements for Streptomycin sulfate for sterile use

Test for sterility on non- [illegible] (32 [illegible] 5 [illegible]) "injectable preparations [illegible].

[illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible] RS [illegible] 1 [illegible] IU [illegible] 0.25 [illegible].

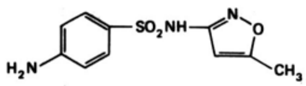
SULFAMETHOXAZOLUM

Sulfamethoxazole [illegible]

$C_{10}H_{11}N_3O_3S$:**Molecular formula** [illegible]

253.3 :**Relative molecular mass** [illegible]

[illegible] :**Graphic formula**



[illegible] :**Chemical name**

N^1-(5-Methyl-3-isoxazolyl)sulfanilamide: 4-amino-*N*-(5-methyl-3-isoxazolyl)benzenesulfonamide; CAS Reg. No. 723-46-6.

[illegible] :**Description** [illegible].

[illegible] :**Solubility** [illegible] 50 [illegible] (~750) TS [illegible] 3 [illegible] R [illegible].

[illegible] :**Category** [illegible].

[illegible] :**Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 99.0% [illegible] 101.0% [illegible] $C_{10}H_{11}N_3O_3S$ [illegible].

[illegible] :**Identity tests**

- [illegible] A [illegible] B [illegible].

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 5 [illegible] 0.5 [illegible] (~80) TS [illegible] 5 [illegible] 0.1 [illegible] R [illegible] 1 [illegible] (~40) TS [illegible].

C: [illegible] 0.1 [illegible] "General identification tests [illegible] (119 [illegible] 1 [illegible]) [illegible].

.°ÿ172 – 168 ⁝**Melting range** ǿȦƮÔƥɍǟ ȯȦƒ

ĶƠ Ȣʐòʐŋ ʐŁ ȦȶÕ ǿȦƓǹɍǟ ȯʐŸƬ ƘȒƠ ŌDZɉ ȟ1.0 ŌȶȞƥÊȦ ⁝**Heavy metals** ǦŸƐŌǯǿǟ (ǥǟÂŸȦǿǟ) ȷåȦȞƫǟ ǦŌȦÂÛǿǟ ÆÊǵ ȷåȦȞƫǟ ƾʐƥƬ ȸƐȞƚ Û(127 ǦƜȦÔǿǟ Û1 ÆŸÕǟ) 3 ǿǟȦDZʠǟ "ǦŸƐŌǯǿǟ ȷåȦȞƫǟ ŌDZɉ ȂÆΣǟ ǿȦƓǹɍǟ" ȷǟʐȦȝ .ȟ/ÿǟȦȡȘȦÒŋ 20 ȸȝ ÆȦÂȦ ɍ Û(128 ǦƜȦÔǿǟ Û1 ÆŸÕǟ) A

ȯʐŸƬ ȸŋ Ōŋ 2.0Ș ǿȦƫǟ ȸŋ Ōŋ 8.0 ȸŋ ȷȦÂŋ Ž ȟ 0.40 ǿǟÆŌŋ ǟǟØȦ ⁝**Solution in alkali** ȂʐŸŌǿǟ Ž ȯʐŸǂǟ .ƗʐȦò ȯʐŸǂǟ ȷʐÒȦ ÜVS (ȯ/ȯʐŋ 1) ÂƐÕȦƥǽ ÿʐȦåʐÔǿǟ ÆƐÊÕȘǿÆƐŁ

.ȟ/ŋŸŋ 1.0 ȸȝ ÆȦÂȦ ɍ ⁝**Sulfated ash** ĶȦŸÊƫǟ åȦŋȦǿǟ

5.0 ȸŋ ȦǯÕÛ ÆŌȦȦ ɍ Ü°ÿ105 ǥǿǟȦǵ ǦDZǿå Ž ĶǟȦǯǿǟ ȷàʐǿǟ ʔøƥǵ ʐȦƶ ⁝**Loss on drying** ʐƐȦDZʐƥǿȦǽ ÆŌȦǿǟ .ȟ/ŋŸŋ

ǦǟǟȦȩ ǥǿǟȦǵ ǦDZǿå Ž R ȷʐǟȦÒǿǟ ÆƐÊÕÛ ƜəȦƥ ȸŋ ƂȦȷǟ ǿȦƫǟ ȸŋ Ōŋ 50 ȝŋ ȟ 1.0 ȸǺÊƚ ⁝**Acidity** ǦȑʐȶΣǟ ȦȞÎȶÕ ŌȶȞƥÊȦ ÛǦǵȦïȦǿǟ ȸŋ Ōŋ 25 ǿǟÆŌŋ ȦȦȞƚ ÛǦïȦȴȘ Û°ÿ20 ǥǿǟȦǵ ǦDZǿå ƂÛ ǦȝȦÊǽ åƎƚ .ȨəȦȩå 5 ǥÆŋ °ÿ70 VS (ȯ/ȯʐŋ 0.1) ÿʐȦåʐÔǿǟ ÆƐÊÕȘǿÆƐŁ ȯʐŸƬ ȸŋ Ōŋ 0.35 ȸŋ ȦǯÕÛ ÆŸÛƥƚ ɍ ÜTS ȯʐƥȦǯȦǗ/ƙȦǿȦǯʐ ȯʐƐʐ ȯʐŸƬ .ȦȞÎȶŸǿ ʔÛèʐǿǟ ǦÛŌȦǿǟ ʔŸȝ ȯʐÔƜŸǿ

ǦŌƐȩȦǿǟ ǦŌǦÛǿǟ ǟǟȦÎƥèǟ" ȷǟʐȦȝ ĶƠ Ȣʐòʐŋ ʐŁ ȦȶÕ ǿȦƓǹɍǟ ȨǦÛƚ ⁝**Related substances** ǦǿȦÎƫǟ åǟʐƫǟ 20 ȸŋ ȷȦÂŋȘ ǦŸȣŋ ǥåȦȶÕ R3 ȦÒƐŸƐÊǿǟ ǦŋƳŁ ȯȦȶȞƥèȦǽ Û(84 ǦƜȦÔǿǟ Û1ÆŸÕǟ) "Thin-layer chromatography .ÕȦƜƥŋ ǿʐÛÕ R ÆƐŋȦŋǿʐʐ ŌƐǯƐŋ ƜəȦƥ ȸŋ ƗÆǵǟȘ ƗȶDzǵ ÛR ȯʐƥȦǯƐƫǟ ȸŋ ƙȶDzǵ ÛR ÿǿʐʐȘǿʐŸÒǿǟ ȸŋ ƗȶDzǵ TS (ȯ/ȟ750~) ȯʐƥȦǯȦʠǟ ȸŋ ÿʐDzǵ 9 ȸŋ ȷȦÂŋ Ž ƙȦƥǟ ƙȯʐŸƬ ȸŋ ȦƥȘȦÒŋ 10 ǦƜƐȦÔǿǟ ʔŸȝ ƳÔȦȦŋ ȨǦÛƚ .Ōŋ 1 ŌÕ Ž ǿȦƓǹɍǟ ǥåȦŋ ȸŋ ŋŸŋ 2.5 Ȃʐʒ ⁝(A) ȯʐŸǂǟ ÛTS (ȯ/ȟ260~) ȦƐʐŋɉǟ ȯʐŸƬ ȸŋ ƗÆǵǟȘ ƗȶDzǵȘ Ûǟǟ ȦÎƥèɍǟ ǥƘDzǵ ȸŋ ǦƜƐȦÔǿǟ ƫȦƥ ÆȞǽ .Ōŋ1 ŌÕ Ž RS ÆƐŋƳƐȦȦŸÊǿǟ ȸŋ ÿǟȦȡȘȦÒŋ 12.5 Ȃʐʒ ⁝(B) ȯʐŸǂǟȘ Ž ȸǺÊǩ ÛTS ȯʐƥȦǯȦǗ ȬȦǿʐȦŸÊǿǟ Ȑƥ ȯʐŸƜŋ ǦȦȦÕǿǟ ǦƜƐȦÔǿǟ ǽȦƚ.ǥȦƓȦØƫǟ ȦǺƓǩ ʔøƥǵ ǿǟʐƮǟ Ž ʐDzƥǿ ÕȦƥǩ ȷÛ ȸÒʐ) ǦŌƐȩå 15 ǥÆŋ ǦŌŸȣŋ ǥƘDzǵ Ž àȘȦƥȦǿǟ ȸəȦǹÆǿ ǿʐȦǿǟ ʔŸȝ ôȦƗȞȘ ÛǦŌƐȩå 30 ǥÆŋ °ÿ105 ǥǿǟȦǵ ǦDZǿå ȸŋ ȟ10 Ȃʐƥʒ ȯʐŸƬ ƂÛ ǥȦÛŌʐ ǥȦÛȩ TS (ȯ/ȟ700~) ȬȦǿʐȦŸÊǿǟ Ȑƥ ȯʐŸƬ ǦʐȦȑǿǽ ǦȦàȘȦƥȦǿǟ ȸəȦǹÆǿǟ ÆƗʐƥǩ ǦŌƐȩå 15 ǥÆŋ ùʐǟå ǿǟʐŁ ǿȦƐǩ Ž ǦƜƐȦÔǿǟ ȝȑʐǩ .(Ōŋ 100 Ž R ÿʐƐèȦǩʐǦǿǟ ÆȦåʐȦ ȸŋ ȟ 3Ș R ÿʐȦåʐÔǿǟ ĶȦȦƥƥ ǥåȦȝÛ Ōǿȩ ʐDzƥǿ ƗȦǿȘȦȑ ȷȦÕ ǟǽÛ ÕȦƥƚ .TS ȯʐƥȦǯȦǗ/ ƙŋÛ ƜəȦƥ ƙŸƐǯȦǗ (ŌƐƥʐȦƥ -1) -N ÆȦǿʐŸÕȘǿÆƐŁ ȯʐŸƜŋ ǽȦƙȘ ȦǯÕÛ ÛǦƐÊƐəȦǿǟ ǦȞŌǦǿǟ ǿȦȦǯƥèȦǽ ÛA ȯʐŸǂǟ ȸŋ ȷƥȦǩ ǦȞŌǽ ǦȦÛ ȷʐÒǩ ɍ .ǿȦƮȦǿǟ ǿʐȑ Ž ǟǟȦÎƥèɍǟ ÙÛƯ ÒƜȦȦȘ ǽȦǿǟ .B ȯʐŸǂǟ ȸŋ ȷƥȦǩ ƜøƥǿǟȬŸǩ ȸŋ ǥÆï

[illegible] 1 [illegible]) "Nitrite titration [illegible]" [illegible] **Assay** [illegible]

[illegible] 20 [illegible] 40 [illegible] 0.5 [illegible] (143 [illegible] 0.1) [illegible] TS [illegible] 70~) [illegible] 15 [illegible] R [illegible] .VS [illegible] 0.1) [illegible] 1 [illegible] .VS [illegible] 25.33 [illegible] $C_{10}H_{11}N_3O_3S$.

[illegible]

Additional requirements for Sulfamethoxyzole for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]"

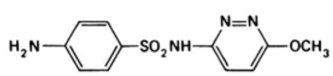
SULFAMETHOXYPYRIDAZINUM

Sulfamethoxypyridazine [illegible]

$C_{11}H_{12}N_4O_3S$:**Molecular formula** [illegible]

280.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

N[1]-(6-Methoxy-3-pyridazinyl)sulfanilamide; 4-amino-*N*-(6-methoxy-3-pyridazinyl)benzenesulfonamide; CAS Reg. No. 80-35-3.

[illegible] :**Description** [illegible]

[illegible] TS [illegible] 750~) [illegible] :**Solubility** [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

%99.0 ... **General requirement** :
%101.0 ... $C_{11}H_{12}N_4O_3S$ ...

:**Identity tests**

• ... A ... B ... C.

A: ... "Spectrophotometry in the infrared region" (43 ... 1) ... *reference spectrum* ... RS ...

B: 0.05 ... "General identification tests" (119 ... 1) ...

C: 20 ... 10 ... (100~ ...) TS ... 0.1 ... (50 ...) TS ...

:**Melting range** 180 – 183°

:**Heavy metals** ... 1.0 ... (127 ... 1) 3 ... (128 ... 1) A ... 20 ...

:**Sulfated ash** 1.0 ...

:**Loss on drying** ... 105° ... 5.0 ...

:**Acidity** 1.0 ... 50 ... 70° ... 5 ... 20° ... 25 ... 7.0 ... 0.35 ... (0.1 ...) VS.

:**Related Substances** ... (84 ... 1) "Thin-layer chromatography ... R3 ...

[illegible] 20 [illegible] (750~ [illegible]) [illegible] 9 [illegible] 10 [illegible] 2.5 [illegible] :(A) [illegible] (260~ [illegible]) [illegible] TS [illegible] 1 [illegible] RS [illegible] 12.5 [illegible] :(B) [illegible] 1 [illegible] 15 [illegible] 30 [illegible] °105 [illegible] TS [illegible] TS(700~ [illegible]) [illegible] 100 [illegible] R [illegible] 3 [illegible] R [illegible] 10 [illegible] .TS [illegible] (-1)-*N* [illegible] 15 [illegible] A [illegible] .B [illegible]

[illegible] "Nitrite titration [illegible]" [illegible] **Assay** [illegible] 50 [illegible] 0.5 [illegible] (143 [illegible] 1 [illegible] .VS(0.1 [illegible]) [illegible] TS (70~ [illegible]) [illegible] .$C_{11}H_{12}N_4O_3S$ [illegible] 28.03 [illegible] VS (0.1 [illegible]) [illegible]

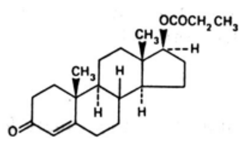
TESTOSTERONI PROPIONAS

Testosterone propionate [illegible]

$C_{22}H_{32}O_3$ **:Molecular formula** [illegible]

344.5 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



:Chemical name [illegible]

17*β*-(1-Oxopropoxy)androst-4-en-3-one; 17*β*-hydroxyandrost-4-en-3-one propionate; CAS Reg. No. 57-85-2.

[illegible] :**Description** [illegible]

[illegible] TS (ò/ȟ 750~) [illegible] :**Solubility** [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %97.0 [illegible] :**General requirement** [illegible] $C_{22}H_{32}O_3$ [illegible] %102.0 [illegible]

:**Identity tests** [illegible]

- [illegible] B [illegible] A [illegible]

A: [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] *reference spectrum* [illegible] RS [illegible]

B: [illegible] Thin-layer chromatography [illegible] kieselguhr R1 [illegible] (84 [illegible] 1 [illegible]) "spectrum [illegible] 10 [illegible] 5 [illegible] R [illegible] 90 R [illegible] 16 [illegible] 6 R [illegible] 4 [illegible] R [illegible] 9 [illegible] 2 [illegible] 1.0 [illegible] :(B) [illegible] 1 [illegible] 1.0 [illegible] :(A) [illegible] 12 [illegible] 1 [illegible] RS [illegible] 10 – 5 [illegible] °120 [illegible] 10 [illegible] °120 [illegible] TS [illegible] – 4 [illegible]

[illegible] (365 [illegible]) [illegible]
.B [illegible] A [illegible]
.°121 [illegible] :C

[illegible] 10 [illegible] :**Specific optical rotation** [illegible]
. $[\alpha]_D^{20^\circ C}$ +81 to +91°

750~) [illegible] 10 [illegible] 0.50 [illegible] :**Solution in ethanol** [illegible] Yw2 [illegible] TS [illegible] .(43 [illegible] 1 [illegible]) "Colour of liquids [illegible]

5.0 [illegible] °105 [illegible] :**Loss on drying** [illegible]

[illegible] :**Related substances** [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 0.5 R [illegible] 8 R [illegible] 92 [illegible] R [illegible] R [illegible] 9 [illegible] 5 [illegible] 1 [illegible] 0.20 [illegible] :(B) [illegible] 1 [illegible] 20 [illegible] :(A) [illegible] 10 [illegible] °110 [illegible] 10 [illegible] °110 [illegible] TS [illegible] A [illegible] (365 [illegible]) [illegible] .B [illegible]

TS (750~) [illegible] 20 [illegible] :**Assay** [illegible] 100 [illegible] 5.0 [illegible] 100 [illegible] 241 [illegible] 1 [illegible] RS [illegible] $C_{22}H_{32}O_2$ [illegible] 0.03 ± 0.50 [illegible]

TETRACYCLINI HYDROCHLORIDUM

Tatracycline hydrochloride ǄžǐǂǀǐƨƐþǂǁǁƐ ǫǐþǋǂǀǋþǫǐǉ

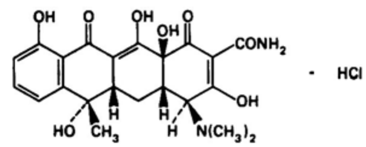
Tetracycline hydrochloride (non-injectable) ǄžƽƟǂǁ üǤƽǁƐ þǐƷ ǄžǐǂǀǐƨƐþǂǁǁƐ ǫǐþǋǂǀǋþǫǐǉ

Tetracycline hydrochloride, sterile !ǐƽƴǁƐ ÛǄžǐǂǀǐƨƐþǂǁǁƐ ǫǐþǋǂǀǋþǫǐǉ

$C_{22}H_{24}N_2O_8$, HCl ¦**Molecular formula** ǦƁǺǺÂƨǟ Ǧ8ǁÔǟǟ

480.9 ¦**Relative molecular mass** ǦǁǤÊǺǟǟ ǦƁǺǺÂƨǟ ǦŸǪÒǟǟ

¦**Graphic formula** ǦǂǫǺǁǤȶǟ Ǧ8ǁÔǟǟ



¦**Chemical name** ɄǝǺǁȶǁÒǟǟ ȴèɼǟ

(4*S*,4a*S*,5a*S*,6*S*,12*αS*)-4-Dimethylamino-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide monohydrochloride; [4*S*-(4*α*,4a*α*,5a*α*,6*β*,12a*α*)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; CAS Reg. No. 64-75-5.

.ǦǶǝǟÀǟǟ ƇǼƷ ÜÀÀòǕ ÛɃøƺŸǣ ȧƺǶÊȵ ¦**Description** Ƶòƶǟǟ

ǟǟȿǣ Ƙȡ ÜTS(ó/ȟ 750~) óƺǫǺǮǺɋǟ ȸȵ ŏÂDZ 100 Žȿ ŏǺȶǟ ȸȵ ŏǟÂDZǕ 10 Ž ǟǟȿǣ ¦**Solubility** ǦǁǫǺǣȿǾǟǟ

.R Ƙǫǂǟ Ž ɼȿ ÛR ÿøƺƺȿøƺŸÒǟǟ Ž ɼȿ R ȷƺǪǁèǂǟ Ž ǺǁŸȶƷ

.Ƀƺǁǵ ǻǺȒȵ ¦**Category** ǦǺȂǟǟ

.ŏƺȒǟǟ ȸȵ ǦǁȶƬ ÛÿǺÒǵǖǣ ǦÕŸ8ȵ ǦǺȿǺǵ Ž ƙŸÒǁèǟÀǪǪǟǟ ǼǺøƺŸÕȿøǼǁȽ ȘǺǵ Ǽƶ ¦**Storage** ȸǺÂǺǪǟǟ

ǦǁƺǺȓɋǟ ǧǺǤŸÛǪȶǟ ɄøǤŸǩ ǥǻǺȶǟ ȷǕ ȻǕ ǦȶǁÕȟǟǟ ƙŸÒǁèǟÀǪǪǟǟ ǼǺøƺŸÕȿøǼǁȽ ǦǁȶÊǪǟǟ ƘÎǩ ¦**Labeling** ȴǁèƺǪǟǟ

.ɁÀǹǂǟ ǦȶǁÕȟǟǟ ǧǟÀȒǶǪÊȶŸǟ ȿǕ ɄøǺÕΣǟ ŏǺÛƷRǟ ÕȶȟǪÊǩ ȷǕ ȸÒƹȿ ƙŸÒǁèǟÀǪǪǟǟ ǼǺøƺŸÕȿøǼǁȽ ÕDZǂ

ŏǺȽǺǣ ǧǟǣ ÕǁǟǺƬ Ž ǦƷÀÊǣ ƙŸÒǁèǟÀǪǪǟǟ ǼǺøƺŸÕȿøǼǁȽ ÕÒǺǪǺ ¦**Additional information** ǦǁƺǺȓǕ ǧǺȵƺŸȟȵ

ÕøǼǪǺ ƙŸÒǁèǟÀǪǪǟǟ ǼǺøƺŸÕȿøǼǁȽ ȷǖƺ ÛŏƺȒǟǟ ǟǺǁȡ Ž ɁøǪǵ .7 ȧƺƺ ŏǺȽǺǣ ǧǟǣ ÕǁǟǺƬ Ž ÕȩǕ ǦƷÀÊǣȿ Û2 ǨƠ

.ɁŸƷǂǟ ǥøǟÀΣǟ ǧǺDZøǻ Ž ȶÀèǕ ÕÒǺǪǟǟ ȷƺÒǺȿ ÛɃƺΣǟ ƿǺǺȶǟ ǦǣƺüÀǟ ôÀȟǪǟǟ ȸƷ ǰǺøǼǪǟǺǣ

ƻǛȝ A ǦÊǺǞÕţä ÆÊǵ ЗǪƩ ǺŋÆǺȝ ƙǛÒƐèǟǺǪǪä ÆǺøȤǛÕşøÆƐŁ ɃȤǪƷ :**General requirement** ӯǺȞöä ÆǛÛǪţä
ŌÕǺ ɍ Ǻŋ ƻǛȝ B ǦÊǺǞÕţä ÆÊǵ ЗǪƩ ǺŋÆǺȝş Û$C_{22}H_{24}N_2O_2$,HCl ȸŋ %102.0 ȸȝ ÆǺÂǺ ɍş %96.0 ȸȝ ŌÕǺ ɍ Ǻŋ
. ǦÀǺÔä gáǺţä ƂǛ ţȤDZǺöǺǣ ǺƵǺǪǛõ ÆÊȞǶ ÛŊǛŋ 1 Ōõ Ž ǦƐöşá gÆǵş 950 ȸȝ

:**Identity tests** ȟǐŇǰŇǁƐ l ƐƥƑǴǂǪƐ

"Thin-layer chromatography ǦŌƐȩǺöä ǦŌǤÛöä ā äǺ ÎǪèä" ȷäȤǺȝ ǨƠ ȣȤòȤŋ ȤŁ ǺŧŌ øǺǤǪǹɍä ȜǺƶ :A
120 ȣǺȒŀ :ƂǺǪöä ȤȞǺöä ƻǛȝ ǺȒŢ ɃäȤǐȤǛè ȣ¥ȡş ǦŌǛȣȟ Ƙȡ gƘDzǵ ȯǺŧȞǪèǺǣ ȸȮö Û(84 ǦȞǺÔöä Û1 ÆǛŎä)
Ż ÜǺǹǿ Ǩȩş ȸŋ ¢Ȓǹ ɃǺƶş gÆǵǟş ǦȝǺè gÆŋ øäǺŌǪè¥ö ǰǺÂţä ȭǺǪŀ ÛR ƘŋȤäøǺÒöä ȸŋ ȟ 0.275 ƂǛ öǺţä ȸŋ Ōŋ
.7.0 ƂǛ öǺȽǺǤöä ŌǺÆȞǪö TS(ȯ/ȟ 80~) ӯȤǺáȤÔöä ÆƐÊÕşøÆƐŁ ȯȤǛȚ ȸŋ ǞȤǺõ ǞŧDzǵ ÕǺȞȞǪöä öǺǺǪǙ ǰǺøÆǪöǺǣ ȣǺȒǺ
ǦǛȣȣŋ gáǺŋ ƻǛȝ ȯȤÔȞǛö (Ōŋ 80 – 60 gáǺȝ) öǺţä ȸŋ ǦƐȤǺõ ǦƐŧõş R1 äȤǐȤǛȄöä ȸŋ ȟ 30 ǰǺÂţä äØŁ ƂǛ ȣǺȒǺ
ǴǝǺÀÔöä ŌŧȞǪÊǩ .ǦȤǺȣöä gøäǺǵ ǦDZøá Ž ȤDzǪö ȭǺǪǩş ÛȽǛŋ 0.4 ǦǪǺǺǯǣ ǦŌǤÛǣ ǴǝǺÀÔöä ƻǛÛǩ .ÆèǺǺŋ ȧǺÊǩä ǧäǣ
ŌDZɉ ."related substances ǦöǺÎţä ááȤţä" øǺǤǪǹǟş ǦǺȤTä øǺǤǪǹä ȸŋ ŌÒö ǦǤèǺǺŋ ǦȤǺȞŋ ÆȞǣ ŌÒÎöä äØõ ǦƐǛÛţä
.(ǦǣȤùǺöä) gşäÆǺöä øǺǪǙ ǺȚȚǩ Ǧǵ ÛTS Û4.5 öǺȽǺǣ ǧäǣ ǧäǺǪè/ǧǺÂÊȤ ǦǝøäȧƐȯȤǛȞŋ ǦȞƐǺÔöä æǺǩ ǦǺȤTä øǺǤǪǹä
.ǦŌƐȩá 30 gÆŋ °ӯ 50 gøäǺǵ ǦDZøá Ž ǦȞƐǺÔöä ȤǺDzȴ

gáǺŋ ȸŋ ŊǛŋ 5.0 ā äØŀ :ȝùǺÊöä öȤȒöä ȸŋ ǦƐŧȚ ȷȤÒǩ ǺŧÆǣ gǺïǺǤȟ ȯǺŧȞǪèɍä ŌǤȩ ǦƐöǺǪöä ŌƐöǺ ǂä ǺȒȞȴ
ÛRS ƘǛÒƐèǟǺǪǩ ɄÊõşǚ ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0 ÛRS ƘǛÒƐèǟǺǪǩ øȤǛõ ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0 ÛøǺǤǪǹɍä
ÜŌŋ 10 øäÆŌŋ ȽDzǵ ƻȝ ȯȤÔȞǛö R ȯȤǪǯƐţä ȸŋ ȣǺõ øäÆŌŋ Ž RS ƘǛÒƐèǟǺǪǪä ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0ş
ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0ş RS ƘǛÒƐèǟǺǪǪä øȤǛõ ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0 ā äØŀ .A ȯȤǛǂä ȷȤÒǺ äØŁş
.B ȯȤǛǂä ȷȤÒǺ äØŁş ÜŌŋ 10 øäÆŌŋ ȽDzǵ ƻǛȝ ȯȤÔȞǛö R ȯȤǪǯƐţä ȸŋ ȣǺõ øäÆŌŋ Ž RS ƘǛÒƐèǟǺǪǩ ɄÊõşǚ
5.0ş RS ƘǛÒƐèǟǺǪǪä ɄÊõşǚ ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0 ÛRS ƘǛÒƐèǟǺǪǩ øȤǛõ ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ 5.0 ā äØŀ
äØŁş ÜŌŋ 10 øäÆŌŋ ȽDzǵ ƻǛȝ ȯȤÔȞǛö R ȯȤǪǯƐţä ȸŋ ȣǺõ øäÆŌŋ Ž RS ƘǛÒƐèǟǺǪǪä ÆǺøȤǛÕşøÆƐŁ ȸŋ ŊǛŋ
.C ȯȤǛǂä ȷȤÒǺ

ȯȤǛȞŋ ȄǪǺDzǪŋş ĘƐȩá ȤǗ ƻǛȝ æǺǩş ÛCş ÛB ÛA ŌƐöǺǂä ȸŋ ǬŌ ȸŋ ǺǪöşǺÒŋ 1 ǦȞƐǺÔöä ƻǛȝ ǰÔǺǺŋ ĘǤÛŀ
.(Ōŋ 8 ǦääǺȩ) gşäÆǺöä øǺǪǙ ǺȚȚǩ ƻøǪǵ TS (ȯ/ȟ 50) ǺƐŌǺǪǣ ȸǺÆǺƘǤöä ŌƐǯȞŋ ɄǪ¥Ǫ

6ş ÛR ȷȤǪƐèɉä ȸŋ ǞŧDzǵ 30 ÛR ŌƐǯǺǬä ǧǺǪƐèǙ ȸŋ ǞŧDzǵ 60 ȸŋ ǞƵÂŋ ɃȤƷ ɃØöä ȭǺȞǪţä øȤÛöä ÆÔŀ
øȤÛöä ȝŋ âǺǪ ƻǛȝ ǺȚǛȞƶ ɍ āȤǛèüǣ gƘDzƩä Ž ǦȞƐǺÔöä ȝȑȤǩ .ǦŌǛȣŋ Ƙȡ ā äǺÎǪèä gƘDzǵ Ž öǺţä ȸŋ ӯȤDzǵ
øȤÛǪƐö ȭǺǪǩş ȭǺȞǪţä øȤÛöä Ž ǦȞƐǺÔöä ȄŧȣǩŻ .gÆǵǟş ǦȝǺè gÆŋ øǺǺǤǺǣ ǦäǺÎȟ ǴǤÔǪö ǦȞƐǺÔöä ȭǺǪǩ .ȭǺȞǪţä

ô ÀĤǩ ÛöäζŢä Ž ǷDzǪö õÀǬǩ ā äÀ Î Ǫèɍä ǵKDzǵ ȡŋ ǦĦɄÀÔöä ţÂǪ ÆĤǟ .Ļè 15 ǦζÀÊŋ ʔøǪǵ ā äÀ Î Ǫèɍä ÙÛƯ
.(ÀǪŋζǫÀǫ 365) ǦĘDzÊÀÀǦöä àζζ ǦĤ ì ɉä Ž äøζζ ā äÀ Î Ǫèɍä ÙÛƯ ÒĦɄÀŞ ÛTS(ò/ȟ 260~) ÀǪζŋɉä òζŸŢ øÀǺǦö
ȡŋ ǰǪÀǩ ɄøǪöä Õ̃Ÿǩ Ʒŋ ǵÆ Î öäş ÀŢŢţäş Ʒęζţä Ž A òζŸǂä ȡŋ ǰǪÀǩ dzζȑζǟ ǦŸÔÀÀŋ ǦĘÊĘǝø Ʒ̃ǟ ǫŸǪ Ęζäζǫǩ
.B òζŸǂä ȡŋ ǰǪÀǩ ɄøǪöä Ʒ̃Ǧöä Ʒŋ ÀŢÀŋ ɈÀǪÀǪä Ęζäζǫǩ ÛC òζŸǂä

ɃØöä ɄDzÊÀÀǟ – Àƥ Ǘ ɈζǏ Ō̃Ò Î ǪÀ ÛTS (ò/ȟ 1760~) Õ̃ÀøζÀŸÊöä Ȑƥ ȡŋ Ōŋ 2 øäÆŌŋ ŋŸŋ 1 ƂǗ ȣÀȒǂ :B
.öÀţä ȡŋ Ōŋ 0.1 ǦζÀȑüǟ ÀÀòɉä ƂǗ òÆǦǪÀ

General ǦŋÀĤöä ȣäÀĤǪèɍä ğäøÀǦǪǹäˮ ɈäζÀƷ ǨƠ ȣζòζţä B Ō̃ƷÀÀǪöä Ōŋ/ȟ 0.05 ÂĘ̃õÀǪǟ òζŸŢ ɄÛĤÀ :C
.(121 ǦĦÀÔöä Û1 ÆŸǑä) ğäÆÀøζŸÒŸö ÂɃţŀ Ō̃ƷÀÀǪ̃õ "identification tests

Ȑƥ Ž Ōŋ/ŋŸŋ 10 ÂĘ̃õÀǪǟ òζŸŢ Ō̃ţĤǪÊǂ :**Specific optical rotation** ɄƷζÀöä ɃÀÔǦöä ÀÀşÆǪöä
. $[\alpha]_D^{20°C}$ = - 239 to - 258° ÜǦÀÀǑä ǵÀţä ƂǗ ţζDzÀöÀǟ ÆÊĦɄǂş VS (ò/òζŋ 0.01) Õ̃ÀøζŸ̃õşøÆĘŢä

ζŸĘ̃õ0.6 ȡƷ ÆÀÂÀ ɍ) ȐÀǺÀŋ Ȕȣȑ ǨƠ °ÿ60 ǵøäÀǵ ǦDzøǻ Ž ȡǺÊǂ :**Loss on drying** ǷĘÀDzǪöÀǟ ÆŌ̃Àöä
.ȟ/ŋŸŋ 20 ȡŋ Àǯ̃õǗ ÆŌ̃ÀÀ ɍ Üğ ÀƷÀè 3 ǵÆŋ (ĘǦǝä Ļŋ 5 Ǧǝ äÀę şǗ òÀÒèÀǟ

.2.8 – 1.8 ÛŌ̃ŋ/ŋŸŋ 10 ÂĘ̃õÀǪǟ òζŸŢ ǒÀȽÀǟ ŋŸǦÀ :**pH value** ǒÀȽÀǦöä Ǧţęę

ǦŌ̃ǦÛöä ā äÀ Î Ǫèäˮ ɈäζÀƷ ǨƠ ȣζòζŋ ζȽ Àţ̃õ øÀǦǪǹɍä ʔÀƶ :**Related substances** ǦǒÀ Î ţä ǻäζţä
ɈäζÀƷ ǨƠ ğÀȒǵ ɄøǪöä ǦĦɄÀÔöä òÀţĤǪèÀǟ Û(84 ǦĦÀÔöä Û1 ÆŸǑä) "Thin-layer chromatographyǦŌ̃ęÀöä
òζŸŢ VS (ò/òζŋ 0.1) ÂĘ̃õÀǪǟ ÿζÀǻζÔöä ǦĘǝÀÀǪ ğÀǪÀÆÀǗ òζŸŢ ȡŋ äȣÀ̃õ ĻDzǵ ƂǗ ȣÀȒǂ .A ǦÀζŢä øÀǦǪǹä
ȆǫÀDzǪŋ Ō̃Ò Î ǟ ǦĦɄÀÔöä æÀö òζŸǂä äØȽ Ō̃ţĤǪÊÀş Û7.0 ƂǗ ǒÀȽÀǦöä Õ̃ÀÆĤǪö TS (ò/ȟ 80~) ÿζÀǻζÔöä ÆĘỄõşøÆĘȽ
.ǦŌ̃ęǻ 30 ǵÆŋ °ÿ50 ǵøäÀǵ ǦDzøǻ Ž ǦĦɄÀÔöä ǷÀDzǂ .ǵşäÆÀöä øÀǪǗ ÀŢŢǩ ʔøǪǵ

øäÆŌ̃ŋ Ž øÀǦǪǹɍä ǵÀÀŋ ȡŋ ȟ 0.10 ā äØǂ :ƷüÀÊöä ǒζȒöä ȡŋ ʔţƠş ÛòÀţĤǪèɍä ŌǦę ǵÀ ì ÀǦŋ ǦĘǒÀǪöä ŌĘǒÀǂä ÀȒƠ
10.0 ƂǗ A òζŸǂä ȡŋ Ōŋ 2.5 ǷÀǺǂ .A òζŸǂä Ɉζ̃ÒǂäØȽş Ü Ōŋ 10 ĻDzǵ ʔŸƷ òζÔĦŸö R òζǫÀǯĘţä ȡŋ ȣÀ̃õ
Ž RS ƙŸÒĘèäÀǪǩşøÆĘŒǗ ɄøǦÀǗ -4 ÆÀøζŸ̃õşøÆĘȽ ȡŋ ŋŸŋ 5.0 ā äØÀ .B òζŸǂä ɈζÒÀ äØȽş ÜR òζǫÀǯĘţÀǟ Ōŋ
10 ƂǗ K òζŸǂä ȡŋ Ōŋ 2 ǷÀǺǂ .K òζŸǂä ɈζÒÀ äØȽş ÜŌŋ 20 ĻDzǵ ʔŸƷ òζÔĦŸö R òζǫÀǯĘţä ȡŋ ȣÀ̃õ øäÆŌ̃ŋ
ȣÀ̃õ øäÆŌ̃ŋ Ž RS ƙŸÒĘèäÀǪǩ ɄøǦÀǗ -4 ÆÀøζŸ̃õşøÆĘȽ ȡŋ ŋŸŋ 5.0 ā äØǂ .C òζŸǂä Ɉζ̃ÒǂäØȽş ÛR òζǫÀǯĘţÀǟ Ōŋ
òζǫÀǯĘţÀǟ Ōŋ 10 ƂǗ L òζŸǂä ȡŋ Ōŋ 2 ǷÀǺǂ .L òζŸǂä ɈζÒǂäØȽş ÜŌŋ 8 ĻDzǵ ʔŸƷ òζÔĦŸö R òζǫÀǯĘţä ȡŋ
ȡŋ ȣÀ̃õ øäÆŌ̃ŋ Ž RS ƙŸÒĘèäÀǪǩşøÆĘŒǗ ÆÀøζŸ̃õşøÆĘȽ ȡŋ ŋŸŋ 5.0 øäÆŌ̃ŋ ā äØÀ .D òζŸǂä ɈζÒǂäØȽş ÜR
ÛR òζǫÀǯĘţÀǟ Ōŋ 10 ƂǗ M òζŸǂä ȡŋ Ōŋ 2 ǷÀǺǂ .M òζŸǂä ɈζÒÀ äØȽş ÜŌŋ 20 ĻDzǵ ʔŸƷ òζÔĦŸö R òζǫÀǯĘţä
R òζǫÀǯĘţä ȡŋ ȣÀ̃õ øäÆŌ̃ŋ Ž RS ƙŸÒĘèäÀǪǩøζŸ̃õ ÆÀøζŸ̃õşøÆĘȽ ȡŋ ŋŸŋ 20 ā äØÀ .E òζŸǂä ɈζÒÀ äØȽş

Anhydroderivatives

Assay

"Non-aqueous titration"

$C_{22}H_{24}N_2O_8,HCl$

Microbiological ǦǿζĔΣǟ ğǟǻǺȒȶŶǿ ǦĚǅζǿζĔǟşÀǾŢǟ ǦÊǺǺŎţǟ" ɉǟζǺȝ ǨƠ 8ζǒζɳ ζĿ Ǻȶõ ǦÊǺǺŎţǟ ĘǦÛǨ :B şǛ 8241 NCTC)*Bacillus pumilus* ǦǹζÔȞǿǟ (a) ǺɳǛ ȯǺȶȞǪèǺǟ Û(155 ǦĦǺÔǿǟ Û1 ǼŶŎǟ) "assay of antibiotics 4.5 ǒǺĿǺǟ ÛǦȶĔŎȝ ğǺǺÊζ Ǧǝøǟǻ Û6.6 – 6.5 ǦĚǝǺŒ ǒǺĿǺǟ ȝɳ Cm1 ţǿà Ǜèş ÛøǺǪǹȑǟ Ʉǵ ȹǝǺǾõ(14884 ATCC şǛ Û°ÿ39 – 37 ƙǟ ȹȒΣǟ ǥøǟǺǵ ǦǅǿǻşÛ(IU Ǧǿşǻ ǥǼǵş 20ş 2 ƙǟ ǥǻǺȝ) ƙŶǾĔèǟǺǪǪǟ ȹɳ ǼèǺǺɳ ÂĔõǺǨ ÛTS ɄǝǺŒ ǒǺĿǺǟ ȝɳ Cm1 ţǿà Ǜèş ȯǺȶȞǪèǺǟ ÛøǺǪǹȑǟ Ʉǵ ȹǝǺǾõ (11778 ATCC) *Bacillus cereus* ǦǹζÔȞǿǟ (b) Ǧǿşǻ ǥǼǵş 2 – 0.5 ƙǟ ǥǻǺȝ) ƙŶǾĔèǟǺǪǪǟ ȹɳ ǼèǺǺɳ ÂĔõǺǨ ÛTS 4.5 ǒǺĿǺǟ ÛǦȶĔŎȝ ğǺǺÊζ Ǧǝøǟǻ Û6.0 - 5.9 ȹɳ ǦĔŶȝǺǺŶǿ ǖÛǺŶǿ ǥǼȶǪȞţǟ ǻşǼΣǟ ǺǮĔζ ɉζǾǨ ɍ ŎǾÎǟ ɄĿ ǦÊǺǺŎţǟ Ǧǝǻ .°ÿ33 – 30 ƙǟ ȹȒΣǟ ǥøǟǺǵ ǦǅǿǻşÛ(IU ǼΣǟ ɉζǾǺ ɍ .ǥøǼŎţǟ ǦĔŶȝǺǺǿǟ ȹɳ %105 ȹɳ ǺǯõǛ ɍş %95 ȹɳ ŎǝǛ estimated potency ($P = 0.95$) ǥøǼŎţǟ БǛ ţζǅǺǿǺǟ ǦǿζÊƮ ÛɳŶɳ 1 Ŏõ Ž IU Ǧǿşǻ ǥǼǵş 950 ȹɳ ŎǝǛ ($P = 0.95$) ǥøǼŎţǟ ǦĔŶȝǺǺŶǿ ǖÛǺŶǿ ɃζŶȞǿǟ ǼȶǪȞţǟ .ǦǺǺǾǟ ǥǻǺţǟ

!ǐşyǁǁ ǅǐǂǀǐƨǫþĦǁǁ ǭǐþǋǂǀǋþǭǐǀǰ ǖǕǓ ƕǐǯƑƮǟ ǀƑǤǂƲĐǅ

Additional Requirements for Sterile Tetracycline Hydrochloride

Sterility testing of ǦǿζĔΣǟ ğǟǻǺȒȶŶǿ ǦɳǺŎȞǿǟ øǺǪȑǟ" ɉǟζǺȝ ǨƠ ǻøş Ǻţ ǼĔǅǪÊǨ :Sterility ǦɳǺŎȞǿǟ .ǒǺÎ8ǟǺǟ ǴĔǏǺǪǿǟ øǺǪȑǟ ǒǟǺǅǛ ĘĔǦÛǨ ȝɳ (162 ǦĦǺÔǿǟ Û1 ǼŶŎǟ) antibiotics"

!ǐşyǁǁ ǖǂǅyƗƨǘǁǁ ǭyǅǁǁ ǅǐǂǀǐƨǫþĦǁǁ ǭǐþǋǂǀǋþǭǐǀǰ ǖǕǓ ƕǐǯƑƮǟ ǀƑǤǂƲĐǅ

Additional requirements for Tetracycline hydrochloride for sterile use

Test for sterility of non- ȹŎĦŶǿ ǦŶǟǺŎǿǟ Ƙɖ ğǟǺȒĦǪÊţǟ ǦɳǺŎȝ ŎǅǰøǺǪȑǟ" ɉǟζǺȝ ǨƠ ǻøş Ǻţ ǼĔǅǪÊǺ .(ǦǺÂĔŶƠqǟ ǦȞǦÛǿǟ Ž 32 ǦĦǺÔǿǟ Û5 ǼŶŎǟ) "*injectable preparations*

øǺǪȑǟ" ɉǟζǺȝ ǨƠ 8ζǒζɳ ζĿ Ǻȶõ øǺǪȑǟ ĘǦÛǺ ¦**Bacterial endotoxins** ǦĔɳζǪǺƨǟ ǦĔŶȑǟǼǿǟ ğǺǺǺǺØǿǟ ɍ Û(ǦǺÂĔŶƠqǟ ǦȞǦÛǿǟ Ž 30 ǦĦǺÔǿǟ Û5 ǼŶŎǟ) "Test for bacterial endotoxins ǦĔɳζǪǺƨǟ ǦĔŶȑǟǼǿǟ ğǺǺǺǺØǿǟ ŎǅǰǺ .ɳŶɳ 1 Ŏõ Ž RS ɄŶȑǟǼǿǟ ɉǺǺǺØǿǟ ȹɳ IU Ǧǿşǻ ǥǼǵş 0.5 ȹɳ ǺǯõǛ Ƀζȝ

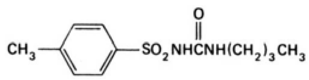
TOLBUTAMIDUM

Tolbutamide ǭǐǅǰƑǂǋǤǁǋǂ

$C_{12}H_{18}N_2O_3S$ ¦**Molecular formula** ǦǺǺǺÂƨǟ Ǧ8ĔÔǿǟ

270.4 ¦**Relative molecular mass** ǦǦÊǺǿǟ ǦǺǺǺÂƨǟ ǦŶǪǾǿǟ

[illegible] :**Graphic formula**



[illegible] :**Chemical name**

1-Butyl-3-(*p*-tolylsulfonyl)urea; *N*-[(butylamino)carbonyl]-4-methylbenzenesulfonamide; CAS Reg. No. 64-77-7.

[illegible] :**Description** [illegible].

[illegible] :**Solubility** [illegible] 10 [illegible] (~750 [illegible]) TS [illegible]
[illegible] R.

[illegible] :**Category** [illegible].

[illegible] :**Storage** [illegible].

[illegible] :**Additional information** [illegible]
[illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 99.0% [illegible] 101.0% [illegible]
[illegible] $C_{12}H_{18}N_2O_3S$ [illegible].

[illegible] :**Identity tests**

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43). [illegible]
[illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 0.2 [illegible] 8 [illegible] (~700 [illegible]) TS [illegible] 30
[illegible] C [illegible].
[illegible] (~300 [illegible]) TS [illegible] 30 [illegible] 30 [illegible]
[illegible] (0.1 [illegible]) VS [illegible] 2 [illegible] 0.2 [illegible]
[illegible] 1 [illegible] 10 [illegible] (10 [illegible]) TS [illegible] 10 [illegible] R

[illegible] 30 [illegible] TS (100 [illegible]) [illegible] 2.7 [illegible] TS1 [illegible] -4 [illegible] TS (80~ [illegible]) [illegible] 2.5 [illegible]

[illegible] 105 [illegible] 4 [illegible] B [illegible] :C [illegible] 136 °[illegible].

Melting range [illegible]: 126 – 130 °[illegible].

Heavy metals [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 3 [illegible] (128 [illegible]) A [illegible] (127 [illegible]) 20 [illegible].

Sulfated ash [illegible] 1.0 [illegible].

Loss on drying [illegible] 105 °[illegible] 5.0 [illegible].

Related substances [illegible] "Thin-layer chromatography" [illegible] (84 [illegible]) R1 [illegible] 15 [illegible] TS (260~ [illegible]) [illegible] 3 [illegible] R [illegible] -2 [illegible] R [illegible] 5 [illegible] (A) [illegible] 10 [illegible] (B) [illegible] 1 [illegible] 0.05 [illegible] - 4 [illegible] R [illegible] 1 [illegible] 110 °[illegible] 10 [illegible] TS1 [illegible] TS [illegible] TS [illegible] 5 [illegible] A [illegible] B [illegible].

Assay [illegible] 0.55 [illegible] 30 [illegible] TS (750~ [illegible]) [illegible] TS [illegible] 20 [illegible] R [illegible] TS [illegible] 0.1 [illegible] VS [illegible] 1 [illegible].

.$C_{12}H_{18}N_2O_3S$ ሙŋ ŊŸŋ 27.04 ùẓỈỎΛ VS(ȯ/ȯẓŋ 0.1) ÂĔÕÃǪǣ ğẢǫẓǣÀỎǟ ሙŋ БẢʅǟ ÿẓΛẩẓÔǟ

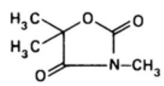
TRIMETHADIONUM

Trimethadione ǅǈǰǿȡƑǩǏǅǏƥȾ

$C_6H_9NO_3$ ¦**Molecular formula** ǦƁẢΛÂƨǟ Ǧ8ĔÔǟ

143.1 ¦**Relative molecular mass** ǦĔǤÊĀǟ ǦƁẢΛÂƨǟ ǦŸǪỎǟ

¦**Graphic formula** ǦƁǫẢĔǤȼǟ Ǧ8ĔÔǟ



¦**Chemical name** ȖǝẢĔȶĔỎǟ ʆȅɽǟ

3,5,5-Trimethyl-2,4-oxazolidinedione; CAS Reg. No. 127-48-0.

.ǦĀĔẢǹ ǦΛøẓẓẢÕ ÛǦȞǝǟÀǟ ÜɈẓŸǟ ǦƹǼɜ ÛǦĔǤĔǤǵ ğǟøẓŸǣ ¦**Description** ȤǑȤǟ

.R ÿøẓẓȘøẓŸỎǟȘ R ƘǭɟǟȘ TS (ȯ/ȟ 750~) ȯẓǫẢǯΛɋǟ Ž ɈẢǣȘØǟ Àǵ ÜǑẢƫǟ Ž ǟǣȘǽ ¦**Solubility** ǦĔǫẢǣȘØǟ

.ǯŸǪǹǟ ǻẢȒŋ ¦**Category** ǦẢƋǟ

.ẩøẢǣ ɈẢỎŋ Ž ȘẢƠȘ ÛǟǼĔǅǅ ǦÕŸ8ŋ ǦΛȘẢǵ Ž ɈẓΛẩẢǯĔƹÀǪǟ ȘẢǵ Ǽƺ ¦**Storage** ሙΛÂẢǪǟ

REQUIREMENTS ƘǦǻǐȢǩǅǲ!ƒ

%101.0 ሙɜ ǼΛÂΛ ɽȘ %98.0 ሙɜ ŎǟΛ ɽ Ẫŋ ʔŸɜ ɈẓΛẩẢǯĔƹÀǪǟ ɃẓǪɜ ¦**General requirement** ÿẢȞǟ ǼŸÛǪƫǟ

.ǦẢẢŎǟ ǥẩẢƫǟ БǗ ƫẓǅǅÀǟẢǣ ǦǣẓÊƮ Û$C_6H_9NO_3$ ሙŋ

¦**Identity tests** ȟǐǈǋǇǁƐ lƐƥƑǴǬǁƐ

.Dȿ Cȿ B ǦǭŸǯǟ ğǟøẢǤǪǹɽǟ ŎÕ ȘǗ ȻẩÀẢŋ A øẢǤǪǹɽǟ ĘĔǤÛǩ ሙỎȤ •

ǒǟÀȶƩǟ ƘƠ ǦȞɨɟǟ ǦŌÛΛŋ Ž ȖǝẓȒǟ ȤĔÛǟ ǟẢĔȘ" ɈǟẓΛɜ ƘƠ ȣẓǑẓŋ ẓȽ ẢȶÕ ǸȞẢǟ ĘǤÛΛ :A

ƘƠ ǦȞɨɟǟ Ž ȋẢÔǪŋɽǟ ȤĔù ĘǣẢÛǪΛ .(43 ǦȞẢÔǟ Û1 ǼŸŎǟ) "Spectrophotometry in the infrared region

.ɈẓΛẩẢǯĔƹÀǪŸǒ *reference spectrum* ȖǶǅǅẢǗǟ ȤĔÛǟ ɜŋ ȘǗ RS ɈẓΛẩẢǯĔƹÀǨ ሙŋ ǰǪΛΛ ɃØǟ ȤĔÛǟ ɜŋ ǒǟÀȶƩǟ

ÜTS (ȯ/ȟ 15) ÿẓΛøẢǤǟ ǼĔÊÕȘøǼȽ ȯẓŸƮ ሙŋ Ŏŋ 2 øǟǼŎŋ Ŏŋ/ŊŸŋ 20 ÂĔÕÃǪǣ ȯẓŸƮ ሙŋ Ŏŋ 5 БǗ ȣẢȒȽ :B

.ǿǫÀöä ʔŸʒ ǦæÀèƅ ǰϘÀǩ

30 ǥÆn ƱəÀn ӯÀþ ʔŸʒ TS (ȯ/ȟ 80~) ӯǫÀǻǫÔöä ÆŁÊȭşǿÆŁ ȯǫŸҬ ȸn Ōn 10 ʒn ȟ 0.5 ǿäÆŌn ȸÅÊł :C

ʔøϘǵ TS(ȯ/ȟ 70~) ȭÀǿǫŸȭşǿÆŁTä ȐϸǿǾШ ȣÀȒÀş ÛǰŸǯöä Ž ǻƎÀ ÛȐÀÅÀn ǈDzǵ ʔøϘǵ ÀÅǤł ÛǦŌȨǻ

ÜTS(ȯ/ȟ 25) ȭÀÆÀÆΣä ÆÀǿǫŸȭ ȸn ɉÀǩÀÛȩ Ōn 0.5 ƁÜ ȣÀȒÀ .R ȄȶÎöä ǻÀǤʒ ȧǿǫö ǦǤÊÀöÀæ ǞȒnÀǵ ɉǫÒÀ

.D ǿÀǤϘȁɍä ŌDzɉ ȯǫŸǂä ȸn ƱȩÀǤöä ʔŌǤϘÊÀ .ȨnÀȡ ÀÀȍÜ ɉǫö ŌÒÎϘÀ

ÜǥÀn Ōȭ Ž Ōn 10 ȯÀȶȞϘèÀæ ÛR ƘϘɉÀæ ǧäÀn ϙƳϘ C ǿÀǤϘȁɍä ȸn ǰϘÀÀ ƁǾöä ȯǫŸǂä ȸn ƱȩÀǤöä ȌŸÅϘÊł :D

ȐÀÀȞϘö ǦÀşÀȞŸö ƱŸȁäÆöä ǴÛÊöä (ǰȞÊł) ȭȞȴş ǦŌȨǻ 30 ǥÆn ƱəÀn ӯÀþ ʔŸʒ ƘϘɉä ǧÀȍƳȁ ȶǫȶƒ ÀÅǤł

.(ȭÀÀǩǫǣşÂÀä ƱÊȭşǿÆŁ – α Ȑþ) °ӯ80 ǦææÀǂ ÛǿÀȚÔϕɍä ǥǿäÀǵ ǦDzǿǻ ÜǥǿǫŸǤöä

.ȨǤÊn ȤŁÀѲ ɉşǻ ǦÀŁȞŀ Û°ӯ 47 – 45 :**Melting range** ǿÀȚÔϕɍä ȯÀƒ

.ȟ/ȠŸn 1.0 ȸʒ ÆÀÂÀ ɍ :**Sulfated ash** ǨÀŸÊʈä ǻÀnÀöä

5.0 ȸn Àǯȭ̈Ü ÆŌÀÀ ɍ Ü°ӯ105 ǥǿäÀǵ ǦDzǿÆæ ǨæÀǯöä ɉàǫöä ʔøϘǵ ȤÀƶ :**Loss on drying** ȤŁÀDzϘöÀæ ÆŌÀöä

.ȟ/ȠŸn

"Gas chromatography ɃàÀȣöä äÀÀÎϘèɍä" ɉäǫʒ ǨƠ ȣǫȍǫn ǫŁ Àȶȭ ǦÊÀŌʈä ȨǤÛǩ :**Assay** ǦÊÀŌʈä

(1) :ǦŁöÀϘöä ǦϘƳǯöä ŌŁöÀǂä ŌȶȞϘÊł .TS ȯǫϕÀǯÀÜ ŌŁÆǫ –2 ȯǫŸҬ ƱŸȁäǻ ɃǿÀŁȞȶȭ ŌȶȞϘÊÀ .(101 ǦȞÀÔöä Û1 ÆŸŌä)

R ȯǫϕÀǯŁʈä ȸn ȣÀȭ ǿäÆŌnş TS ȯǫϕÀǯÀÜ ŌŁÆǫ –2 ȯǫŸҬ ȸn Ōn 5 ǿäÆŌn RS ɉǫÀǻÀǯŁǫÀǩ ȸn ȟ 0.10 ƁÜ ȣÀȒÀ

ʔŸʒ ȯǫÔȞŸö R ȯǫϕÀǯŁʈä ȸn ȣÀȭ ǿäÆŌn Ž ǦȍǫȞÀʈä ǥǻÀʈä ȸn ȟ 0.20 äÀǾÀ (2) ÛŌn 10 ǈDzǵ ʔŸʒ ȯǫÔȞŸö

ȯǫϕÀǯŁʈä ȸn ȣÀȭ ǿäÆŌnş TS ȯǫϕÀǯÀÜ ŌŁÆǫ –2 ȯǫŸҬ ȸn Ōn 5 ǦȍǫȞÀʈä ǥǻÀʈä ȸn ȟ 0.20 ƁÜ ȣÀȒł (3)ş Ōn 10

ǈè 0.4 ƱŸȁäÆöä ÀÛŌöäş ӯ 1.5 ¢öǫù ƱDzÀDzà ǻǫȶʒ ǦŌÀÀÛöä ȻǾŁ ŌDzÜ ȸn ŌȶȞϘÊł .Ōn 10 ǈDzǵ ʔŸʒ ȯǫÔȞŸö R

ʔŸʒ ǦȶʒÆn R ȯǫÒŁŸȣöä ƙŸǯÀÜ ǦŁəÀÀϘ ǧÀÆÊÒè ȸn ȟ 10 ȸn ǦÀöǘn adsorbent ǥÀϘǘȶn ǥÀn ȸn ǦŁǫÀȭ ǦŁȶÒæ ǫÎҬ

Û°ӯ105 ǥǿäÀǵ ǦDzǿǻ Ž ǻǫȶȞöä ʔŌǤϘÊł .ȐȶΣÀæ ÀȚŸÊȡ Ź ƱøϘöä Silanized keiselguhr R4 ǥÀn ȸn ȟ 90

Û1 ŌŁöÀǂä ȸn CS B ÛA äÀÀÎϘèɍä ǧÀÛÛƯ ÀȒȞł .ÆȚŸöä ȸøÀǘ ȣÀÎÒȠş ŌnÀǵ àÀȣȭ R ƙDzşÀϘÀöä ȯÀȶȞϘèÀæş

ȸn ɁǫϘǂä ÆÊƷş ÛCS B ÛA äÀÀÎϘèɍä ǧÀÛÛƯ Ž ǦȶəƳʈä ǥşǿǾöä ǧÀǵÀæ ȃÀŌǩ .ÆŁǩÀϘöä ʔŸʒ 3ş 2

ǴŁȞÔϘöä ȯÀȶȞϘèɍä ʒȑǫn ʒȑǫÀ .CS A äÀÀÎϘèɍä ǧÀÛÛƯ ȸn ǾȁǘǩƱøϘöä ǧÀϕÀŁǤöä ȯÀȶȞϘèÀæ Û$C_6H_9NO_3$

.ǞÀǿşÀȑ ȭöæ ɉÀȭ äæÜ B äÀÀÎϘèɍä ÙÛƯ ȸn ǰǩÀÀöä

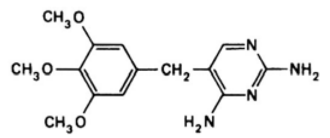
TRIMETHOPRIMUM

Trimethoprim

$C_{14}H_{18}N_4O_3$:**Molecular formula**

290.3 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

2,4-Diamino-5-(3,4,5-trimethoxybenzyl)pyrimidine; 5-[(3,4,5-trimethoxyphenyl)methyl]-2,4-pyrimidinediamine; CAS Reg. No. 738-70-5.

:**Description**

R ... R ... :**Solubility**

:**Category**

:**Storage**

REQUIREMENTS

%101.0 ... %98.5 ... :**General requirement**

$C_{14}H_{18}N_4O_3$

:**Identity tests**

:A

(43 ... 1 ...) "Spectrophotometry in the infrared region

RS ... *reference spectrum*

2 ... (0.005) ... 5 ... 25 ... :B

0.1) ... R ... 1.6 ...

0.4 ... 100 ... VS(

ʔøϘǵ ǦǂφÅϙ ȸÅÊÅʂ ÛʒÂƹ ÛVS (ȯ /ȯɀɳ 0.5) ÕÅøɀÅŸÊöä Ȑƥ ȸɳ Ōɳ 1 ȣÅȒƚ ÛʒÂŧ .TS ǼǂŁǼöÅɳøɀɀ
ÜġǼÎä ǦŸDZɀΣä ȐơʂR ȳøɀɀʂøɀŸÒöä ȸɳ Ōɳ 2 ǦǵÅïÀöä БǕ ȣÅȒƚ .ǴïÀƚʂ ǦɀÅ8öä ǥøäÀǵ ǦDZøǻ БǕ ǻƎƚ .ɹÅǼŸ8öä
.(ÀϘɳɀφÅφ 365) ǦǂDzÊÅAǦöä ȧɀɀ ǦȞïɟä Ž ÒӇÅǨ ÅɳǼÅʒ ȳøɀɀʂøɀŸÒöä ǦŌǦü Ž ÀȒǹǕ ĘöüǨ ŎÒÎϘÅ
.°ȳ200 ǦäÀȩ ÛøÅȚÔφɼä ǥøäÀǵ ǦDZøǻ :C

.ȟ/ɳŸɳ 1.0 ȸʒ ǼÅÂÅ ɼ :**Sulfated ash** ǨÅŸÊƫä ǻÅɳÀöä

10 ȸɳ ÀʒõǕ ǼŌÀÅ ɼ Ü°ȳ105 ǥøäÀǵ ǦDZøǻ Ž ǨǝÅʒöä ɹäɀöä ʔøϘǵ ȤÀDzƚ :**Loss on drying** ȤǂÀDzϘöÅǝ ǼŌÀöä
.ȟ/ɳŸɳ

ǦŌǂȩǻ 1 ǥǼɳ R ɹɀäÀÒöä ǼǂÊõǕ ȗǝÅϙ ȸɳ БÅʅä öÅƫä ȸɳ Ōɳ 20 ʒɳ ȟ 0.20 ȐǺƚ :**pH value** öÅŁÅǦöä ǦŧǂȩΤ
.8.5 – 7.5 ÛǦǵÅïÀöä öÅŁÅǝ ɳŸǦÅ ÜǴïÀÅʂ

:**Related Substances** ǦöÅÎƫä ǻäɀƫä

• ǼȤ ɹǕ ÀDzÅǨ ǧÅŸŧȞöä Ž ǧÅǼŸŧȞöä ɹɀǹäǻ Ž ɀȚɧ ɀȚɧ .ǞǼǂDZ

ǼŸÒöä) "Thin-layer chrompatography ǦŌǂȩÀöä ǦŌǦÛöä āäÀÎϘèä" ɹäɀÅʒ ǨƠ ȣɀòɀɳ ɀȽ ÅŧõÒӇÅöä ĘǦÛƚ
ȳɀDzǵ 10 ÛR ŌǂʒÅɋä ǧÅϘǂèǕ ȸɳ ǞŧDzǵ 85 ȸɳ ǰÅÂɳʂ ǦŸȣ8ɳ ǥǻÅŧõ R2 ÅŌǂŸǂÊöä ǦɳŸȽ ȯÅŧȞϘèÅǝ Û(84 ǦӇÅÔöä Û1
ŌŧȞϘÊǨ ɹǕ Ǽƶ ÜõÀӇϘɳ øɀÛõ R ȗǝÅɳŸöä ŌǂɳøɀÅöä Ȑƥ ȸɳ ƙŧDzǵʂ ÛöÅƫä ȸɳ ȳɀDzǵ 5 ÛR ȯɀφÅʒǂƫä ȸɳ
ÀϘöʂÀÒɳ 5 ǦӇǂÅÔöä ʔŸʒ ȲÔÅÅɳ ĘǦÛƚ .ĘǦÛϘöä Ȕǹ ȧɀɀ ʅè 17 ǼȞÔǂö ǼÅØƫä õÀϘÅʂ ǦŌŸ8ɳ ƙȡ āäÀÎϘèä ǥƙDzǵ
ÛöÅƫä ȸɳ ǞǼǵäʂ ǞŧDzǵʂ ÛR ȯɀφÅʒǂƫä ȸɳ ǞŧDzǵ 4.5 ÛR ȳøɀɀʂøɀŸÒöä ȸɳ ȳɀDzǵ 5 ȸɳ ǰÅÂɳ Ž ƙÅφä ƙöɀŸȚ ȸɳ
Ōõ Ž øÅǦϘǹɼä ǥǻÅɳ ȸɳ ɳŸɳ 0.080 Ƀɀʒ :(B) ȯɀŸɟäʂ Ōɳ 1 Ōõ Ž øÅǦϘǹɼä ǥǻÅɳ ȸɳ ɳŸɳ 40 Ƀɀʒ :(A) ȯɀŸɟä
ǦӇǂÅÔöä ƫÂφ ǼȞǝ .ǥƙDzӇŸö ĘǦÊƫä ƫÅǦïϘä ǼÅDzϘö ǼøɀɀǦӇǂÅÔöä Ȅŧ8ƙʂ ǥƙDzΣä Ž õÀӇϘƫä øɀÛöä ǼŌƚ .Ōɳ 1
ȧɀɀ ǦȞïɟä Ž āäÀÎϘèɼä ȔÛƯ ÒӇÅʂ ÛĘǝÅȩǻ 5 ǥǼɳ ǻøÅǝ öäɀȽ øÅǂǨ Ž ȤDzϘö õÀϘǨ Ûāäǂ ÀÎϘèɼä ǥƙDzǵ ȸɳ
ȯɀŸȚ ȸɳ ǦÅʂÅÊϘɳ ȳɀDzǵ ʒÂɳ ǰϘÅÅ ɃØöä ÛøɀŸÒöä ɃɀƠ ǦŌŸ8ɳ ǥƙDzǵ Ž ǦӇǂÅÔöä ʒȓɀǨ .(ÀϘɳɀφÅφ 254) ǦǂDzÊÅAǦöä
õÀϘǨʂ ÛġƙDzΣä ƫÅȩ Ž ʒȓɀǨ ÛTS (ȯ/ȟ 70~) ŌÅøɀŸõʂøǼǂȚä Ȑƥʂ Ōɳ/ɳŸɳ 15 ÂǂõÀϘǝ R ȳɀǂèÅǨɀǦöä ǧÅφÅ8ÅɳƘǝ
ǦǵÅǦöä ȗÛȞǨ ɼ ʔøϘǵ ǻøÅǦöä öäɀȚä ȸɳ øÅǂǨ Ž øɀŸÒöä ʒɀǼƙʂ ǥƙDzΣä ȸɳ ǦӇǂÅÔöä ƫÂøÅǨ .ǦŌǂȩǻ 20 ǥǼɳ øäÀŌϘèŸö
ÛTS ǼÅǻɀÅ/ÅÎφ ȯɀŸӇɳ ǦӇǂÅÔöä ǽÅǨ .TS ǼÅǻɀÅ/ÅÎφ ȯɀŸȚ ȸɳ Ōɳ 0.05 ǦɀÅȓǕ Ǽʒ ȧøäǕ ɹɀö БǕ ĘǦÛϘöä Ȕǹ ǨƠ
ǥǼï ÀʒõǕ ÛǦǂÊǝÀöä ǦȞŌǦöä öÅʒϘèÅǝ ÛA ȯɀŸɟä ȸɳ ǰϘÅǨ ǦȞŌǝ ǦǕ ɹɀÒǨ ɼ .øÅȚÅöä öɀȓ Ž āäÀÎϘèɼä ȔÛƯ ÒӇÅʂ
.B ȯɀŸɟä ȸɳ ǰϘÅǨ ȗøϘöä ŌŸǨ ȸɳ

ÀÅÅȞÅʂ ÛR1 ȗDzŸʒöä ŌǂϘèɟä Ȑƥ ȸɳ Ōɳ 30 Ž ÛǦǂüɀǦȒɳ ǦφʂÀɀɳ Ûȟ 0.6 ǦäÀȩ āäØƚ :**Assay** ǦÊÅŌƫä
Non-aqueous ȗǝÅɳŸöä Ȕèɀöä Ž ǥÀÅȞƫä" ɹäɀÅʒ ǨƠ ȣɀòɀɳ ɀȽ ÅŧõÛVS(ȯ/ȯɀɳ 0.1) ŌÅøɀŸõƘǦöä ȐŧШ

29.03 ǜȥἈÖ⋀ VS(ȯ/ȯȥŋ 0.1) ÕǀǿȥŸÕǨǴǟ Ȑ þ ȸŋ Ōŋ 1 Ȫõ .(142 ǴĦȦÔǟ Û1 ǼŸǑǟ) A ǴÕǀÂÛǟ Û"titration .$C_{14}H_{18}N_4O_3$ ȸŋ ŊŸŋ

Ǐ ǽȿƟǁƐ üƑǮɏƾƨ ű ǁ ɱɣǮǁƐ !ĭþǴǊķǮĭþƗ üɯŬ ƕĭʒƑ Ƭǝ ǀ ƑǴǂƲƗǮ

Additional requirements for trimethoprime for parenteral use

ǴĦȦÔǟ Û4 ǼŸǑǟ ȀŢǟ) "*Parenteral preparations* ǴĦÕΣǟ ğǟȀȒĦǪÊţ" øǟ ǴȍȀʅǟ ǵǻşȀȥɟǟ Б Ǣ ǢǮǪÊ⋀ .(56

ƕǐDŽШΘǁɛ üǐǁƑΘDŽǁƐǋ ɓƑƓƗƆƖŰɛ üǐǁƑΘDŽ Û Ƹ Ɩ ƐǋǀǁƐ ƕDŽƏƑƼ

LIST OF REAGENTS, TEST SOLUTIONS, AND VOLUMETRIC SOLUTIONS

LIST OF REAGENTS, TEST SOLUTIONS, AND VOLUMETRIC SOLUTIONS

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.index

R 1 2

VS

TS

FeTS FeR AsTS ...

Cm

International RS

Systéme international .Chemical Reference Substances

SRIP (SI) d'Unites

SRIP .(1963)

d d_{20}^{20} 20°

.20°

Acetate standard buffer TS:

10 TS(~60) 10 10

R VS 1)

.1000

Acetazolamide RS:

R1: R:

---

[1] who International Chemical Reference Substances are available from: WHO Collaborating Center for Chemical Reference Substances, Apotekens Centrallaboratorium, Box 3045, 171 03 Solna 3, Sweden.

ȸŋ Ōŋ 1.0 ǿäÆŌŋ Ōŋ 10 Бΰ ȣÀȒł :*Substances reducting dichromate ğÁŋşÀÒöä ȸǝÀǯö ĠöÂÔÁţä åäζţä*
ŌÀǿζÀŸÊöä Ȑþ ȸŋ Ōŋ 10 ǿǾɯ ȣÀȒÀş Ûvs (ȯ/ȯζŋ 0.0167) ӯζȽèÀǩζĠöä ğÁŋşÀõ ȸǝÀǫ ȯζŸƮ
Ûȯζϔǂä ÀÀşÆǩ ǒÀÀǫÛş .ČÕȽęå 30 gÆŋ ǿäÀÕǫèŸö ōÀǫÀş ČζÀȣöä gǿäÀǵ ČDZǿå Бΰ ȯζϔǂä åƎÀ .TS(ȯ/ȟ1760~)
ÂDZäÀù ÀȒǂä ӯζȽèÀǩζĠöä ÆÀåζÀ ȯζŸƮ ȸŋ Ōŋ 1.5 ȣÀȒÀş ÛåƎł ÛǒÀţä ȸŋ Ōŋ 50 ǿäÆŌŋ ǿǾɯş ǒÙĠæ ȤÀÅł
Ōŋ 3 ȣÀȒÀ Ûvs(ȯ/ȯζŋ 0.1) ÂȽõÀǫæ ӯζÀåζÔöä ğÀÀŸèζȽǫ ȯζŸҤŋ ǿÀҤǫţä åζȽöä ÀÀÀǨł .TS (ȯ/ȟ 80) ÂȽõÀǫæ
ɍ .ĠÀǿşÀȑ ğÀҤȽҤÔǩ ĠÀΰ ʔÀΘş gÆȽÀɩ gÀÀÀǨŋ ÂDZÀǩ .ĠÀÀƵÀöä ĠÛÕǫ Бΰ ȯζòζöä āÀǅ ÆÀȝ TS ÀÎÀöä ȯζŸƮ ȸŋ
.VS (ȯ/ȯζŋ 0.1) ӯζÀåζÔöä ğÀÀŸèζȽǫ ȯζŸƮ ȸŋ Ōŋ 0.60 ȸŋ Ōęΰ ŌŸƵǫÊÀ

åƎł .ǒÀţä ȸŋ Ōŋ 10 Бΰ Ōŋ 40 ȣÀȒÀ :*Substances reducing permanganate ğÁǫÁȣÀŋǨĠŸö ĠöÂÔÁţä åäζţä*
ōÀǫłş Ûvs(ȯ/ȯζŋ 0.02) ӯζȽèÀǩζĠöä ğÀǫÀȣÀŋǨæ ȯζŸƮ ȸŋ Ōŋ 0.30 ȣÀȒł Û°ӯ15 gǿäÀǵ ČDZǿå ʔǿǫǵ
.ŌŋÀõ ŌÒÎæ (Ƀåǿζöä Àþɉä) ȸŸÀǫÀÕöä ɉζŸöä ȯşÂÀ ɍ ÜĘǝÀęå 10 gÆŋ °ӯ15 gǿäÀǵ ČDZǿå Ž ǿäÀÕǫèŸö
.168 ČҤÀÔöä Ûɪ ÆŸŎä Ž ǿζÎÀţä Ōöæ ŌƮ БÀΣä ÒÀöä Ōȝ

:**Acetic anhydride/ dioxan TS** ɉÀÊõζÀå ŌȽǫèɉä ÆÀäǿÆȽŒΰ ȯζŸƮ
ȯ/ȯζŋ 0.2) R ŌȽǫèɉä ÆÀǿÆȽŒΰ ȸŋ Ōŋ 1 ǿäÆŌŋ R ɉÀÊõζÀÆöä ȸŋ Ōŋ 50 Бΰ ȣÀȒł :*Procedure ǒäÄDZqä*
.(ÂĠÀÀÕǩ

ȸŋ Ōõ Ž C_2H_3ClO ȸŋ %98.0 ȸȝ ŌÕÀ ɍ Àŋ ʔŸȝ ɃζǫƷ C_2H_3ClO :**Acetyl chlroride R** ŌȽǫèɉä ÆÀǿζŸõ
.(ÂÕǵɍ ÀƮǫä) B ČÊÀÀÕţäş A ČÊÀÀÕţä
.ÂÆDZ ȤȽÀǹ ÀÀòΰ ɉζŸæ şΰ ɉζŸöä ĆÆȝ ÛȣÀò ŌǝÀè :*Description Ȥòζöä*
ȸŋ Ōŋ 1 ȣÀȒł ÛǒÀţä ȸŋ Ōŋ1 ȝŋ Ōŋ 1 ǿäÆŌŋ ǿǾɯ ŌŋÀǨł :*Phosphorous compound ǿζÀÊÀöä ğÀĠõÀŋ*
ȯζŸƮ ȸŋ Ōŋ 10 ȣÀȒÀ ÛǒÀţä ȸŋ Ōŋ 20 ǿäÆŌŋ ȤÀƸ ÛåƎÀ ÛȹÁÊł ÛTS(ȯ/ȟ1000~) ŌÀÀǫÀöä Ȑþ
ŌÒÎǫÀ ɍ ÜƙǫȝÀè gÆŋ °ӯ40 ĠæäÀę gǿäÀǵ ČDZǿå Ž ǿäÀÕǫèŸö ōÀǫÀş TS ŌÀÀǫÀöä Ȑþ/ӯζȽǫζŋɉä ğäÆĠȽöζŋ
.ÀÀòΰ ɉζŸæ ĠæÀèǿ

ȸŋ БÀɭä ӯζÀåζÔöä ÆȽÊõşǿÆȽĽ ȯζŸƮ ȸŋ Ōŋ 50 Ž ÛĞȽùζĠȒŋ ČǫşàζŋÛȟ1 ĠæäÀǅ āäǾł (A) :*Assay ČÊÀÀÕţä*
ȯζÆȥ ȯζŸƮ ȯÀŧǨǫèÀæ Ûvs(ȯ/ȯζŋ 0.5) ŌÀǿζÀŸÊöä ȐŧɯÀÀǨÀş Ûvs(ȯ/ȯζŋ 1) ÂȽõÀǫæ ğÀǫζæÀÒöä
ÂȽõÀǫæ ğÀǫζæÀÒöä ȸŋ БÀɭä ӯζÀåζÔöä ÆȽÊõşǿÆȽĽ ȯζŸƮ ȸŋ Ōŋ 1 Ōõ .ÀǨÎŧõ TS ȯζǫÀǯÀΰ/ƙÀöÀǯζ
Ōŋ 250 ɭDZǵ Бΰ A ȯζϔǂä ȸŋ ȯÆǨţä ŌǝÊöä ȤÀÅł (B) .C_2H_3ClO ȸŋ ŋŸŋ 7.850 ùζÀÒÀ VS (ȯ/ȯζŋ 1)
ğÁŋşÀõ ȯζŸƮ ȯÀŧǨǫèÀæ Ûvs (ȯ/ȯζŋ 0.1) ÂȽõÀǫæ ČȒÀöä ğäÀǫȹ ȯζŸҤŋ ȼÀŋ Ōŋ 50 ÀÀǨÀş ÛƷÂƩ ÛǒÀţÀæ
ȟ 7.850 ùζÀÒÀ (ȯ/ȯζŋ 0.1) ČȒÀöä ğäÀǫǫ ȯζŸƮ ȸŋ Ōŋ 1 Ōõ .ÀǨÎŧõ TS (ȯ/ȟ 100) ÂȽõÀǫæ ӯζȽèÀǩζĠöä

. C_2H_3ClO

Allopurinol RS

Aluminium R Al (SRIP 1963 29)

Aluminium chloride R $AlCl_3, 6H_2O$ (SRIP 1963 30).

Aluminium chloride TS:

Procedure: 65.0 g R 100

0.5 10

0.5 (v/v) 1.5

4-Aminobenzoic acid R – 4 %98.5 $C_7H_7NO_2$.

Description:

Solubility: 170 9 8

~750 (v/v) TS 50 R.

Melting range: 186 – 189°.

Sulfated ash: 1.0 g/kg.

Loss on drying: 105° 2.0 g/kg.

Assay: 0.3 105°

5 ~420 (v/v) TS 50

15° 25

(v/v) 0.1 VS

R

1 (v/v) 0.1 VS 13.71

$C_7H_7NO_2$.

Storage:

2-Aminobutanol R –2 $C_4H_{11}NO$.

Description:

Miscibility: R.

Mass density: P_{20} = 0.944-0.950 kg/l.

. n_D^{20} =1.450-1.455 :*Refractive index* ƁǿǺÊǑǭǭ ǼĒǺǬ

ǿζŸȚ ȸŋ Ǭŋ 0.5 ȣǺȒƚ ÛTS (ǿ/ȟ 750~) ǿζφǮǺqǟ ȸŋ Ǭŋ 4 Ž ȟ 0.05 ǟǟǾƚ :*Identification* ȣǟǺǶȅɍǟ

.ɄDzÊǺǼ ʝζǒ ǬǑÎǪǺ ÜɄǝǺŋ ÿǺþ ʡŸʒ ǖζǼƚȿ .Ǭŋ/ŋŸŋ 2.5 ǺǼõǺǬǟ triketohydrineden hydrate R

:**4-Amino-6-chloro-1,3benzenedisulfonamide R** ǼĒŋǺφζǺŸȅ ɄǝǺǬ ʝÂǿǺǟ **3** Û**1 -** ȿǿζŸõ **- 6 -** ζǼŋǛ **4**

.$C_6H_8ClN_3O_4S_2$

.ǦɄǝǟǺǒǟ CǼʒ ÛȒǛǛ ȧζɄÊŋ :*Description* ƵǒζǟǟΛ

.R ÿǿζζζŸǑǒǟ Ž ɍȿ ǒǺƫǟ Ž ǺǼŸȶʒ ǟǟȿǽ Ƙɖ ÜTS (ǿ/ȟ 100~) ǺǼφζŋɉǟ ǿζŸȚ Ž ǟǟȿǽ :*Solubility* ǦǼφǺǽȿǾǟǟ

ğǺǒǺÔǪŋǟ R ǿζφǺǮƫǟ Ž Ǭŋ/ÿǟǺɖȿǺǑŋ 5 ǺǼõǺǬǟ ǿζŸǂ îǺÔǪŋɍǟ ƵǼù ƁǼǦǺ :*Identification* ȣǟǺǶȅɍǟ

265 ǦDZζŋ ǿζù Ž ǦǼǒǺÔǪŋqǟ .ǺǪŋζφǺφ 312ȿ ÛǺǪŋζφǺφ 265 ÛǺǪŋζφǺφ 223 ǦǟǟǺȩ ʓǟζŋɉǟ ǿǟζùǛ Ž ǦǼȶȚʒǛ

.($E_{1cm}^{1\%}$ = 640) 64.0 ǦǟǟǺȩ ɄȽ ǺǪŋζφǺφ

.ȟ/ŋŸŋ 1.0 ȸʒ ǼǺÂǺ ɍ Üȟ 2 ǬȟÎƚ :*Sulfated ash* ǨǺŸÊƫǟ ǻǺŋǺǒǟ

:**3-Aminopyrazole-4-carboxamide hemisulfate RS** ğǺǺŸÊǼȶǼȽ ǼĒŋǺÊõζǽǿǺõ **- 4 -** ǿȿǟǟƘǽζǼŋǛ **- 3**

.ǦǼǒȿǻ ǦǼǝǺǼȶǼõ ǦǼȟDZǺŋ ǥǻǺŋ

.ǦǼǒȿǻ ǦǼǝǺǼȶǼõ ǦǼȟDZǺŋ ǥǻǺŋ :**Amitriptyline hydrochloride RS** ƙŸǼǪǦǺǺǪǼŋɉǟ ǼǺǿζŸõȿǿǼȽ

:**FeTS** (ǿ ȟ **100~**) **Ammonia** ǺǼφζŋɉǟ ǿζŸȚ

(ǿ/ȟ 100~) ǺǼõǺǬǟ ǺǼφζŋɉǟ ǿζŸȚ ȸŋ Ǭŋ 5 ǺǺǺ :ƃǺǪǒǟ ǿǺǦǪȵɍǟ ƃǛ TS (ǿ/ȟ100~) ǺǼφζŋɉǟ ǿζŸȚ ǼĒDZǪÊǺ

ÛFeTS(ǿ/ȟ 180) ǬǺǺǪǼÊǒǟ Ȓþ ȸŋ Ǭŋ 2 ÛǒǺƫǟ ȸŋ Ǭŋ 40 ȣǺȒƚ ÛɄǝǺŋ ÿǺþ ʡŸʒ ǺǦǺǺǬǨ ȣǺǺƨǟ ʡǿǪǥ TS

50 ƃǛ ƵǺƸȿ ÛFeTS (ǿ/ȟ 100~) ǺǼφζŸɄŋ ǺǺζŸȩ ǬȟƶÛʓÂȶƚ ÜR ǬǼǪǼȅǛ ζǪǽǺõƘǭ Ȓþ ȸŋ ʝǺǨǺÛȩȿ

.(ƁǻǿȿǺþǛ) ɄŸǺφǺȩ ʝζǒ ǬǑÎǪǺ ɍ ÜǒǺƫǺǼ Ǭŋ

.169 ǦɄǺÔǟǟ Û1 ǼŸǑǟ Ž ǿζÎǺƫǟ ǬǽǼ ǑȚ ƃǺƩǟ ǑǺǟǟ Ǭʒ

ȟ 35 ǦǟǟǺȩ ɃζɄǼǒ ƵǻǺȟ ÛTS (ǿ/ȟ 100~) ǺǼõǺǬǟ ǺǼφζŋɉǟ ǿζŸȚ :**TS** (ǿ ȟ **35~**) **Ammonia** ǺǼφζŋɉǟ ǿζŸȚ

.*d*~0.985 Ü(ǿ/ǿζŋ 2 ǺǦǺǺǬǨ) ǺǪǒ 1 Ǭõ Ž NH_3 ȸŋ

ȟ 17 ǦǟǟǺȩ ɃζɄǼǒ ƵǻǺȟ ÛTS (ǿ/ȟ 100~) ǺǼõǺǬǟ ǺǼφζŋɉǟ ǿζŸȚ :**TS** (ǿ ȟ **17~**) **Ammonia** ǺǼφζŋɉǟ ǿζŸȚ

.*d*~0.992 Ü(ǿ/ǿζŋ 1 ǺǦǺǺǬǨ) ǺǪǒ 1 Ǭõ Ž NH_3 ȸŋ

100 ǦǟǟǺȩ R ǺǼφζŋɉǟ ǼǺǿζŸõ ȸŋ ǿζŸȚ Ƀζʒ :**TS** (ǿ ȟ **100**) **Ammonium chloride** ǺǼφζŋɉǟ ǼǺǿζŸõ ǿζŸȚ

.ǺǪǒ 1 Ǭõ Ž NH_4Cl ȸŋ ȟ

ĞǟăÀę Ƀζʒ R ȳζƗǫζɳɟă ğăÆƓƗōζɳ ȯζŸʈ ¦TS (ȯ ȟ 45) **Ammonium molybdate** ȳζƗǫζɳɟă ğăÆƓƗōζɳ ȯζŸʈ
.ÀǫƗō 1 Ōõ Ž $(NH_4)_6Mo_7O_{24}$ ȸɳ ȟ47

¦**TS** (ȯ ȟ **45**) **Ammonium molybdate / nitric acid** ŌÀÀǫǾōă Ȑƥ ȳζƗǫζɳɟă ğăÆƓƗōζɳ ȯζŸʈ
1000~) ŌÀÀǫǾōă Ȑƥ ȸɳ Ōɳ 500 Ž R ȳζƗǫζɳɟă ğÀÀŸè ȸɳ ȟ 50 øăÆŌɳ ăăØł ¦*Procedure ōăÀDZǭă*
ğăÆƓƗōζɳ ȸɳ ȟ 150 ȧøşå Ž ¥ÔÀÀɳ ăăØł .Ōɳ 2000 ȴDzШ ȧøşå şǕ ǴƗùşÀƯ ǴŸDZζǵ ȯÀȶȞǫèÀǟ TS(ȯ/ȟ
ȯζŸǂă Ž ÛŌÀÀȞǫōă øăÀȶǫèă ʒɳ ÛōÙǴǟ ȯζŸǂă ăØȽ ÆÔł ÛÆÀƎǫōă ÆȞǟ .ƂÀ8ōă ōÀţă ȸɳ Ōɳ 400 Ž R ȳζƗǫζɳɟă
.Ǵı̀Àş ÛÿÀǕ 3 - 2 ǥÆɳ øăÀŐǫèŸō ōÀǫÀ .Ōɳ 1000 ƂǕ ōÀţÀǟ ZÀƩş ɄȒȶΣă
.åøÀǟ ɉÀȮɳ Ž ȘÀƠş .ăÆƗDZ ǦŐŸ8ɳ ÛɉζŸōă ǴƗÀǟ ǴƗDZÀDZà ǥøşøÀę Ž ɉÂƩ ¦*Storage ȸÀÁǫōă*

.(35 ǦȞÀÔōă Û1963 ÛSRIP) NH_4NO_3 ¦**Ammonium nirate R** ȳζƗǫζɳɟă ğăÀǫƥ
ȸɳ ȟ 50 ĞǟăÀę Ƀζʒ R ȳζƗǫζɳɟă ğăÀǫƥ ȯζŸʈ ¦**TS** (ȯ ȟ **50**) **Ammonium nitrate** ȳζƗǫζɳɟă ğăÀǫƥ ȯζŸʈ
.Àǫō 1 Ōõ Ž NH_4NO_3

50 ĞǟăÀę Ƀζʒ R ȳζƗǫζɳɟă ğɾÀÊõǕ ȯζŸʈ ¦**TS** (ȯ ȟ **50**) **Ammonium oxalate** ȳζƗǫζɳɟă ğɾÀÊõǕ ȯζŸʈ
.Àǫō 1 Ōõ Ž $C_2H_8N_2O_4$ ȸɳ ȟ

.(39 ǦȞÀÔōă Û1963 ÛSRIP) $NH_4OSO_2NH_2$ ¦**Ammonium sulfamate R** ȳζƗǫζɳɟă ğÀɳÀÀŸè
ĞǟăÀę Ƀζʒ R ȳζƗǫζɳɟă ğÀɳÀÀŸè ȯζŸʈ ¦**TS** (ȯ ȟ **25**) **Ammonium sulfamate** ȳζƗøǫζɳɟă ğÀɳÀÀŸè ȯζŸʈ
.Àǫō 1 Ōõ Ž $NH_4OSO_2NH_2$ ȸɳ ȟ 25

ȟ 5 ĞǟăÀę Ƀζʒ R ȳζƗǫζɳɟă ğÀɳÀÀŸè ȯζŸʈ ¦**TS** (ȯ ȟ **5**) **Ammonium sulfamate** ȳζƗǫζɳɟă ğÀɳÀÀŸè ȯζŸʈ
.Àǫō 1 Ōõ Ž $NH_4OSO_2NH_2$ ȸɳ

.(40 ǦȞÀÔōă Û1963 ÛSRIP) $(NH_4)_2SO_4$ ¦**Ammonium sulfate R** ȳζƗǫζɳɟă ğÀÀŸè

.ǦƗōşå ǦƗəÀƗȶƗõ ǦƗȞDZÀɳ ǥåÀɳ ¦**Ampicillin RS** ƙŸƗÊƗǤɳǕ

.ǦƗōşå ǦƗəÀƗȶƗõ ǦƗȞDZÀɳ ǥåÀɳ ¦**Ampicillin sodium RS** ƙŸƗÊƗǤɳɟă ȳζÀåζò

.ǦƗōşå ǦƗəÀƗȶƗõ ǦƗȞDZÀɳ ǥåÀɳ ¦**Ampicillin trihydrate RS** ƙŸƗÊƗǤɳɟă ğăøÆƗȽ ɄǫŸǫ

.(42 ǦȞÀÔōă Û1963 ÛSRIP) $C_5H_{12}O$ ¦**Amyl alcohol R** ŌƗɳɟă ȯζȞõ

.ǦƗōşå ǦƗəÀƗȶƗõ ǦƗȞDZÀɳ ǥåÀɳ ¦**Anhydrotetracycline hydrochloride RS** ƙŸȮƗèăÀǫǩşøÆƗŒǕ ÆÀøζŸõşøÆƗȽ

.(43 ǦȞÀÔōă Û1963 ÛSRIP) C_6H_7N ¦**Aniline R** ƙŸƗǫǕ

.ÀǬǒ 1 ǑÕ Ž C_6H_7N ɗŋ ȟ 25 ǦǟǟÀę ɃζȜ R ƙŸĿǬɉǟ ȯζŸƮ :**TS** (ȯ ȟ **25**) **Aniline** ƙŸĿǬɉǟ ȯζŸƮ

.$SbCl_3$ ɗŋ 97.0 ɗȝ ǑǑʌ ɍ Àŋ ɃζȜ .$SbCl_3$:**Antimony trichloride R** ȷζȶĿǬɉǟ ǼʌøζŸÕ ɄǬŸǬ

.ȷζŸǟǟ ǦςǼȝ ğǟøζŸǣ :*Description* ζȌζǟǟ

ǞÀȮȝ ȯζŸƮ ǑǑΪǬʌ Ǽę) R ȳøζζşøζŸȮǟǟ Žş R ǒÀţǟ ţşÂøÀŋ ȯζǬÀǯʌqǟ Ž ǞǼDZ ǡǟşǣ :*Solubility* ǦǬÀǣşǾǟǟ
.(ǞŸĿŸę

ɗŋ Ǒŋ 25 Ž ȟ 5.0 ǡǟǾɫ :*Chloroform-insoluble substances* ȳøζζşøζŸȮǟǟ Ž Ǧǟǟşǿǟǟ ƘǬ ǻǟζţǟ
Ž ζÀΘş ÛR ȳøζζøζŸȮǟǟ ɗŋ ȳÀÊęǕ gǼǶǣ ǦǑǨζǦǟǟ ǑÊ8ǩ Ûȷäζǟǟ ǦǬǟÀŋ ǴĿɨÀǩ ǦǑǨζǣ ƎȝǴɨÀɫ ÛR ȳøζζşøζŸȮǟǟ
.ŊŸŋ 1.0 ɗȝ ÀŒäş ǼʌÂʌ ɍ ǦǟÀǬ ǒÀǬǩ Ü°ȳ105 gøǟÀǵ ǦDZøǻ

ȳζʌǻζÔǟǟ ğǟÀùÀù ɗŋ ȟ 4.0 ɃζȜ ɃǾǟǟ ǒÀţǟ ɗŋ Ǒŋ 30 Ž ÛǴĿùζǦȒŋ ǦǬşäζŋ Ûȟ 0.5 ǡǟǾɫ :*Assay* ǦÊʌǑţǟ
.VS(ȯ/ ȯζŋ 0.1) ǻζĿǟǟ ȯζŸĦŋ ÀʌÀǶʌş ÛR ȳζʌǻζÔǟǟş ƙDZşøǼĿŢǟ ğÀǬζǣÀÕ ɗŋ ȟ 2 ȣÀȒʌ ÛR ȳζĿèÀǩζǦǟǟş
.$SbCl_3$ ɗŋ ŊŸŋ 11.4 ùζÀȮʌ (ȯ/ȯζŋ 0.1) ǻζĿǟǟ ɗŋ Ǒŋ 1 ǑÕ

.ǼùÀǟǟ ǒǟζŢǟ Ž ɗǝÀǹǻ øζÛǬǩ Ǽę :*ǦȚǵŸŋ*

:**Antimony trichloride TS** ȷζȶĿǬɉǟ ǼʌøζŸÕ ɄǬŸǬ

ɗŋ ƃÀʅǟ ȯζǬÀǯʌqǟ ɗŋ Ǒŋ 100 Ž R ȷζȶĿǬɉǟ ǼʌøζŸÕ ɄǬŸǬ ɗŋ ȟ 22 ǡǟǾʌ :*Procedure* ǒǟÀDZqǟ
.ǦǑĿęǻ 30 gǼŋ øǟÀǬèŸǒ ǑÀǬʌş ÛR ǑĿǬèɉǟ ǼʌøζŸÕ ɗŋ Ǒŋ 2.5 ȣÀȒʌ ÛR ȳøζζşøζŸȮǟǟ

ʔǼǵǕ ǼÊɯ R ǸĿǬøÂǟǟ ǼĿÊÕǕ ɄǬŸǬ ÀȒĦɫ :**Arsenic trioxide R1** (ǸĿǬøÂǟǟ) ǑĿǼèøɉǟ ǼĿÊÕǕ ɄǬŸǬ
:ƙǬĿǟÀǬǟǟ ƙǬǑʌÀÛǟǟ

420~) ǑʌøζŸÕşøǼĿŢǟ Ȁ ȹ ǞǒÂDZ 20 ɗŋ ζǟǘţǟ Ʉ8ţǟ ǰʌÀţǟ ɗŋ R ǸĿǬøÂǟǟ ǼĿÊÕǕ ɄǬŸǬ gøζŸǣ ǻÀĦɫ .1
ȳɉǟ ǑǝÀÊŸǒ ǴǦÔʌ ʔøǬǵ ƃÀ8ǟǟ ǒÀţǟ ɗŋ ÀǒøζŸǣ ǻÀĦɫş ğǟøζŸǦǟǟ ȝȶΘ ÛǼʌƎǬǟǟ ǼĦǣ .ǒÀţǟ ɗŋ ǒǟÂDZǕ 5ş TS(ȯ/ȟ
.R ÛζÀƒ ÛÀȮĿŸĿÊǟǟ ǦŋŸȽ ȧζζ ǨǟÀǯǟǟ ȷäζǟǟ ʔøǬǵ ğǟøζŸǦǟǟ ζÀΘ .4.0 ɗŋ ƎÕǕ ǒÀȽÀǣ

.ǼèÀʌŋ äÀȚDZ Ž ǸĿǬøÂǟǟ ǼĿÊÕǕ ɄǬŸǬ ǼĦÔɫ .2

ȷζȮʌ ÛǻƎʌş ǴɨÀɫ ÛǒÀţǟ ɗŋ Ǒŋ 20 Ž ȟ 1.0 ȨǝÀęǻ ȝȒǣ gǼŋ ȷĿŸ8ǟǟ ʔøǬǵ ɗǺÊɫ :*pH value* ǒÀȽÀǦǟǟ ǦȶĿę
.4.0 ɗŋ ƎÕǕ ǒÀȽÀǣ ǦǵÀɨÀŸǒ

gÀÛǑǣ ȀȶȜ .Ǒŋ 10 ȴDZǵ ʔŸȝ ȯζÔĦŸǒ ǒÀţǟ ɗŋ ȣÀÕ øǟǼǑŋ Ž ŊŸŋ 10 ǡǟǾɫ :*Chlorides* ğǟǼʌøζŸȮǟǟ
ʔǑǦʌ ÛVS(ȯ/ȯζŋ 0.1) ǦȒÀǟǟ ğǟÀǬǬ ȯζŸƮ ɗŋ ȷÀǨÀÛę ȣÀȒʌş TS (ȯ/ȟ 1000~) ǑʌÀǬÀǟǟ Ȁ ȹ ɗŋ gǼǵǟş
.ƙǬǑĿęǻ ɗȝ ǑǑǩ ɍ gǼŋ ȷζŸǟǟ ȻǼȝş ǞĿζÀȍ ȯζŸǂǟ

ȳζʌǻζÔǟǟ ǼĿÊÕşøǼĿȽ ȯζŸƮ ɗŋ Ǒŋ 10 ɗŋ ǰʌÀŋ Ž ȟ 5.0 ÂĿÕÀǬǣ ȯζŸƮ ƃǕ ȣÀȒɫ :*Sulfides* ğǟǼĿʌÊǟǟ

.ȷζŸӧä ƇÆʒ ȯζŸǂä ʔŎǤ ÜTS(ȯ/ȟ 80) î ÀȍÀӧä ğÀǬÆèÜ ȯζŸȚ ȸ ȷÀǨÀÛȩ ŏÀʈä ȸ Ŏ 15ş TS(ȯ/ȟ 80~)

Àǯõ Ü ÆŎÀÀ ғ ÜR ÛⱫÀƒ ÛÀȮÆŸÊӧä ǤȠ¥Ⱡ ȧζζ ǨæÀǯӧä ȷàζӧä ʔøǬǵ ⱫÀⱬ :*Loss on drying* ⱫÆÀDzǬӧÀæ ÆŎÀӧä

.ȟ/ȠŸ 0.1 ȸ

.ȟ/ȠŸ 0.1 ȸʒ ÆÀÂÀ ғ :*Sulfated ash* ǨÀŸÊʈä ǻÀȠÀӧä

.ǦÆӧşǻ ǦȽÀÆȶÆõ ǦÆǨDZÀ ǵǻÀ ¦**Atropine sulfate RS** ƙæşÀǩɉä ğÀÀŸè

.$C_{12}H_9N_3O_4$ ÜI ȷζÊÆȡÀ ÜȯζÆèøşÂÀø (şàÜ ŎÆÀζşÀǬ - 4)- 4 ¦**Azo violet R** şàÜ ǦÆDzÊÀÀæ

ÀƥÜ ȧζȞÊ :*Description* Ⱬ ȍζӧä

.ȬȮÀǬӧä ʒ ǦŎζäÀǬ °ӯ193 ǦæäÀȩ :*Melting temperature* ǿÀŢÔǬғä ǥǿäÀǵ ǦDZǿǻ

¦**Azo violet TS** şàÜ ǦÆDzÊÀÀæ ȯζŸȚ

ƙÀǬӧä ƙȶDzǵş R ȸÀζȯζǬӧä ȸ Æǵäş ȽDzǵ ȸ ǰÀÂ Ž R şàÜ ǦÆDzÊÀÀæ ȸ ȟ 0.2 ä äǾÀ :*Procedure* ŏäÄDZɋä

.R ȷÀÊȮȽζȮŸÊӧä ȸ

.(46 ǦȞÀȮÂÔӧä Û1963 ÛSRIP) $Ba(OH)_2,8H_2O$ ¦**Barium hydroxide R** ӯζÀǿÀǤӧä ÆÆÊõşǿÆÆȽ

ƂÀʅä ŏÀʈä Ž R ӯζÀǿÀǤӧä ÆÆÊõşǿÆÆȽ ȯζŸȚ ¦**TS (ȯ ȟ 15) Barium hydroxide** ӯζÀǿÀǤӧä ÆÆÊõşǿÆÆȽ ȯζŸȚ

.ÀǬӧ 1 Ŏõ Ž $Ba(OH)_2$ ȸ ȟ 15 ǦæäÀȩ Ƀζʒ R ȷζæÀȮӧä ÆÆÊõÜ ȾȽÀÀǬ ȸ

.ÆDZäÀù (ȯ/ȟ 15) ӯζÀǿÀǤӧä ÆÆÊõşǿÆÆȽ ȯζŸȚ ÀȒȞȽ ȷÜ Æⱬ :*ǦȚǵŸȠ*

ȾȽÀÀǬ ŎÀÂøÀæ ŎÆȮӧÜ ğäÆÀǿζŸõ ȸ ǰÀÂ ζȽ ¦**Benzalkonium chloride TS** ӯζÆǬζȮӧäÂøÀǤӧä ÆÀǿζŸõ ȯζŸȚ

ŎÀÂøÀæ ŎÆȮӧÜ ğäÆÀǿζŸõ ȸ ȟ 530 ȸʒ ÆÀÂÀ ғş ȟ 470 ȸʒ ŎӧÀ ғ Ȧ Æǵäζӧä ÀǬŸӧä Ž Ƀζʒ .ӯζÆǬζȠɉä ŎÆǯÆȠ

.$C_{22}H_{40}ClN$ ÀŒÜ ʔŸʒ ǦæζÊȚ Ûӯζ ÆǬζȠɉä ŎÆǯÆȠ ȾȽÀÀǬ

.ǦÆǨÀȠşǿÜ ÛǦȞäÀӧä Ü8Àȍ ÛǨȽÀǤӧä ÀÀȍɉä ƂÜ ȷζŸӧä ƇÆʒ ÛŸäÀì ŎȽÀè :*Description* Ⱬ ȍζӧä

.TS(ȯ/ȟ 750~) ȯζǬÀǯÀɋäş ŏÀʈä ʒ ǯşÂȸ :*Miscibility* ǦDZşÀʈä

25 ŎӧÀȽ .Ŏ 100 ȽDzǵ ʔŸʒ ȯζÔȞŸӧ ŏÀʈä ȸ 8Àõ ǿäÆŎ Ž ÛǦÆùζǤȒȠ ǦǬşàζȠ Ûȟ 4 ä äǾÀ :*Assay* ǦÊÀŎʈä

ÛVS(ȯ/ȯζȠ 0.1) ӯζÀǻζÔӧä ÆÆÊõşǿÆÆȽ ȯζŸȚ ȸ Ŏ 10 ÛR ӯǿζζşǿζŸȮӧä ȸ Ŏ 25 8ÀȒÀ ÛǦŸȍÀζ ƂÜ Ŏ

ÛȷÀǬŎǤÛӧä ŎÔÀÀǬӧ õÀǬȽ ÛǾÆÆDZ ȐÀȽ .TS (ȯ/ȟ 50) ÀÆõÀǬæ ÆDZäÀù ÀȒǂä ӯζÆèÀǨζǤӧä ÆÀǻζÀ ȯζŸȚ ȸ Ŏ 10ş

ÛŎ10 ȽDzɯ ǦÆȶõ Ŏõ ÛR ӯǿζζşǿζŸȮӧä ȸ ǦÆζÀȓÜ ğÀÆȶõ ϙŸǯæ ǦȽÀʈä ǦŎǤÛӧä Ȑơ .ӯǿζζşǿζŸȮӧä ǦŎǤù dzÀÛǩ

ȯζŸȞȠ ÀÀÀǨÀş ÛǻⱻȽ ÛTS (ȯ/ȟ 420~) ȬÀǿζŸõşǿÆƮä Ȑƥ ȸ Ŏ 40 8ÀȒȽ .ӯǿζζşǿζŸȮӧä ŎÆӧÀȚ dzÀÛǨş

R ӯǿζζşǿζŸȮӧä ȸ Ŏ 2 8ÀȒÀ .ÀǬȽÀæ ÆÆÀæ ȯζŸǂä ȷζӧ ǴǤÔÀ ʔøǬǵ VS (ȯ/ȯζȠ 0.05) ӯζÆèÀǨζǤӧä ğäǻζÀ

ÆÀǻζÀ ȯζŸȚ ȸ Ŏ 6 ÛŏÀʈä ȸ Ŏ 20 ȸ ǰÀÂ ÀÀÀǨȽ .ȷζŸӧä ƇÆʒ ӯǿζζşǿζŸȮӧä ǴǤÔÀ ʔøǬǵ ǥÀÀǨʈä ʒæÀǬǩş

ӯζȄèǺǩζĞöä ğäåζΛ ȯζŸĦŋ TS (ȯ/ȟ 420~) ȬΛǿζŸȭşǿǼȄTä ȐƥdŋȬŋ 40ş ÛTS (ȯ/ȟ 80) ӯζȄèǺǩζĞöä
.ĞæζŸÛţä VS(ȯ/ȯζŋ 0.05) ӯζȄèǺǩζĞöä ğäåζΛ ĞȄŧȭ ƙǨÀΛǺĦţä ƙæ ȧÀÀöä ȬǯƩ Ü¢ÊǺφ āζŸèɉǺæ (ȯ/ȯζŋ 0.05)
ĞŸϘȮöä ĞζǺǯȭ ƙĦǩ .$C_{22}H_{40}ClN$ dŋŊŸŋ 35.40 ȕζǺȮΛ VS(ȯ/ȯζŋ 0.05) ӯζȄèǺǩζĞöä ğäåζΛ ȯζŸƮ dŋȬŋ 1 Ȭȭ
Determination ĞȄĞÊǺöä ĞŸϘȮöäş ĞŸϘȮöä ĞζǺǯȭ ƙȄĦǩ" ɉäζǺ3 ǨƠ ȣζòζŋζĿ Ǻŧȭ Ʉ3ζǺöä ȬȬǯöä âǺȄȬŋ ȯǺŧĦϘèǺæ
øæ gǿǼȬŋ $C_{22}H_{40}ClN$ øŸö ĞĞÊǺöä ǼÊƠş (31 ĞĦǺÔöä Û1 ǼŸǑä) "of mass density and relative density
.ȯ/ȟ

.gζȬæ ɄdǺΛ ¢φüζ ŏǺţä Ž ȯζŸɨä ȐƩ ǺŋǼǺ3 :ĞŢǵŸŋ

؛**Benzalkonium chloride TS1** ӯζȄφζȮöäÂøǺĞöä ǼΛǿζŸȭ ȯζŸƮ

ĻDzǵ ɂŸ3 ȯζÔĦŸö ŏǺţä dŋ ȣǺȭ ǿäǼȬŋ TS ӯζȄφζȮöäĦĞöä ǼΛǿζŸȭ ȯζŸƮ dŋȬŋ 2 ȤǺƩ :*Procedure* ŏäǺDZqä
.Ȭŋ 100

.(48 ĞĦǺÔöä Û1963 ÛSRIP) C_6H_6 ؛**Benzene R** ɉÂøǺĞöä

.$C_7H_6O_2$ dŋ %99.8 d3 ȬȬΛ ɍ Ǻŋ Ƀζ3 .$C_7H_6O_2$ ؛**Benzoic acid R** ȬΛşÂøǺĜöä Ȑƥ

ÛgÂȄŧŋ ÛĞĦǝäǺöä ÜɉζŸöä ĞƩǼ3 ÛĞǺȄǺǹ ÛĞȄÎΛǿ ğäǿζŸæ şǕ ȐȄæǕ ÛǿζŸĞϘöä ɃşǺȮŋ ȧζĦÊŋ :*Description* Ȥòζöä
.ĞǺȄǺǹ

ÛR ƘϘɉäş TS(ȯ/ȟ 750~) ȯζφǺǯΛqä Ž ɉǺæşǾöä Ǻǵ ÜŏǺţä Ž ɉǺæşǾöä ǴȄĦì :*Solubility* ĞȄφǺæşǾöä
.R ӯǿζζşǿζŸȮöäş

R ȯζφǺǯȄţä dŋȬŋ 200 Ž ȟ 20 āäǾǩ : *Methanol-insoluble substances* ȯζφǺǯΛqä Ž ĞæäşǾöä Ƙď åäζţä
ȬÊȣΛ Ûɉàζöä ĞďǺÀǩ ǴȄìǺǨ ĞȬǩζæ Ǝ3 Ǵ ìǺǩ .ĞȬȄşǻ 30 gǼŋ ȬŋǺȮöä Ʉ3ζDZǺöä ɉÀǺɀǺæ ȬŧĦΛ ȤǯȬŋ ǨƠ ĻȒȚǩş
.ŊŸŋ1.0 d3 ǼΛÂǩ ɍ ĞöǺŧǬ ȭǺϘǩ Ü°ӯ105 gǿäǺǵ ĞDZǿå Ž ȤǺƶş ÛR ȯζφǺǯȄţǺæ ȲŋǺȭ

ȀȬĞÊŋ ȯǺȄĦţä ÛTS(ȯ/ȟ 750~) ȯζφǺǯΛqä dŋȬŋ 15 Ž ÛĞȄüζĞȒŋ Ğφşàζŋ Ûȟ 0.5 ĞæäǺę āäǾΛ :*Assay* ĞÊΛȬţä
ӯζΛåζÔöä ǼȄÊȭşǿǼȄĿ ȯζŸĦŋ ÀΛǺĦǩş ŏǺţä dŋȬŋ 20 ȣǺȒǩ ÛTS ȯζφǺǯΛǛ/ƙǺöǺǯζ ȯζǼǺöä ȯζŸƮ ɂŸ3
ɁÀƶş ĞòζĦǺţä gåǺţä ɉşå ĞȄŸŧĦöä åǺĦǩ .ÀĦÎŧȭ TS ȯζφǺǯΛǛ/ ȯζǼǺöä gÀƥ ȯζŸƮ ȯǺŧĦϘèǺæ ÛVS (ȯ/ȯζŋ 0.1)
dŋŊŸŋ 12.12 ȕζǺȮΛ VS (ȯ/ȯζŋ 0.1) ӯζΛåζÔöä ǼȄÊȭşǿǼȄĿ ȯζŸƮ dŋȬŋ 1 Ȭȭ .ɃǿşÀȓ ǴȄĦÔǩ ɃǕ
.$C_7H_6O_2$

.(50 ĞĦǺÔöä Û1963 ÛSRIP) C_7H_5ClO ؛**Benzoyl chloride R** ȬΛşÂøǺĞöä ǼΛǿζŸȭ

.ĞȄöşå ĞȄǝǺȄŧȄȭ ĞȄĦDZÀŋ gåǺŋ ؛**Benzylpenicillin potassium RS** ƙŸÊǺȄöä ȬΛÂøǺȄ ӯζȄèǺǩζæ

.ĞȄöşå ĞȄǝǺȄŧȄȭ ĞȄĦDZÀŋ gåǺŋ ؛**Benzylpenicillin sodium RS** ƙŸÊǺȄöä ȬΛÂøǺȄ ӯζΛåζò

[illegible] **Bephenium hydroxynaphthoate RS** [illegible]

[illegible] **Betamethasone RS** [illegible]

[illegible] **Bismuth oxynitrate R** [illegible] 4BiNO$_3$(OH)$_2$,BiO(OH) (SRIP) 1963 [illegible] (50 [illegible]

[illegible] **Blue tetrazolium R** [illegible] $C_{40}H_{32}Cl_2N_3O_2$. 3,3-Deianisole-bis-[4,4- (3,5-diphenyl) tetrazolium chloride].

[illegible] *Description:* [illegible] – [illegible]

[illegible] *Solubility:* [illegible] (~750 [illegible]) TS [illegible] R [illegible] R [illegible] R [illegible]

[illegible] *Molar absorptivity:* [illegible] 252 [illegible] 60000.

[illegible] *Suitability test:* [illegible] (~750 [illegible]) TS [illegible] (R [illegible]) [illegible] 105° [illegible] 3 [illegible] 10– 15- 20- [illegible] 30 [illegible] 10 [illegible] 5 [illegible] 50 [illegible] 10- 15- [illegible] TS (~750 [illegible]) [illegible] 20 [illegible] 10 [illegible] R [illegible] 0.05 [illegible] 2.0 [illegible] TS(~750 [illegible]) [illegible] TS [illegible] 2.0 [illegible] TS (~750 [illegible]) [illegible] 90 [illegible] 525 [illegible] 200 [illegible] 0.50.

[illegible] **Blue tetrazolium / ethanol TS**:

[illegible] *Procedure:* [illegible] 0.5 [illegible] R [illegible] (~750 [illegible])TS [illegible] 100 [illegible].

[illegible] **Blue tetrazolium / sodium hydroxide TS**:

[illegible] *Procedure:* [illegible] 2 [illegible]

.TS [illegible] R [illegible] 0.12 [illegible] 3 [illegible] R [illegible]

.(52 [illegible] 1963 [illegible] SRIP) $C_{21}H_{14}Br_4O_5S$:**Bromocresol green R** [illegible]

:**Bromocresol green/ ethanol TS** [illegible]

[illegible] 2.9 [illegible] R [illegible] 0.1 [illegible] :*Procedure* [illegible]

[illegible] TS ([illegible] 710~) [illegible] 5 [illegible] VS ([illegible] 0.05)

.[illegible] 250 [illegible] TS ([illegible] 150~)

.(52 [illegible] 1963 [illegible] SRIP) $C_{21}H_{16}Br_2O_5S$:**Bromocresol purple R** [illegible]

:**Bromocresol purple / ethanol TS** [illegible]

[illegible] TS([illegible] 750~) [illegible] 100 [illegible] R [illegible] 0.05 [illegible] :*Procedure* [illegible]

.[illegible]

:**Bromothymol blue / dimethylformamide TS** [illegible]

R [illegible] R [illegible] 1.0 [illegible] :*Procedure* [illegible]

.[illegible] 100 [illegible]

:**TS ,8.0** [illegible] **Buffer borate** [illegible]

[illegible] 50 [illegible] R [illegible] 0.309 [illegible] R [illegible] 0.25 [illegible] :*Procedure* [illegible]

[illegible] 3.97 [illegible] R [illegible]

[illegible] R [illegible] VS ([illegible] 0.2)

.[illegible] 200

:**TS, 9.0** [illegible] **Buffer borate** [illegible]

[illegible] 8.3 [illegible] 100 [illegible] R [illegible] 1.24 [illegible] :*Procedure* [illegible]

.[illegible] 200 [illegible] VS ([illegible] 1) [illegible]

:**TS, 9.6** [illegible] **Buffer borate** [illegible]

[illegible] 50 [illegible] R [illegible] 0.30 [illegible] R [illegible] 0.25 [illegible] :*Procedure* [illegible]

[illegible] 36.85 [illegible] R [illegible]

[illegible] R [illegible] VS ([illegible] 0.2) [illegible]

.[illegible] 200 [illegible]

:TS, 6.4 ǒǺŁǺǣ Û**Buffer phosphate** ğǺǺÊǺǒǟ Ǵəǿǟǻ ȯƺŶŢ

ȡȠ ƃǺȽǟ ǒǺƫǟ ȡȠ ǾȠ 50 Ž R ȳƺǢèǺǩƺǴǟ ƙǅŞǿǼǢŁ ȖəǺǺǫ ğǺǺÊƺ ȡȠ ȟ 1.36 āǟǾǺ :*Procedure ǒǟǺǅǅǫǟ*

0.2) ǺǢõǺǪǣ ğǺǫƺǣǺǑǟ ȡȠ ƃǺȽǟ ȳƺǺǻƺÔǟ ǼǢÊõŞǿǼǢŁ ȯƺŶŢ ȡȠ ǾȠ 12.60 ȣǺȒǂ ÛR ȷƺǣǺǑǟ ǼǢÊõǕ ȖəǺǺǫ

.ǾȠ 200 ȻǿǼȩ ǈǅƺǵ ɁŶȝ ȯƺÔȞŶǒ R ȷƺǣǺǑǟ ǼǢÊõǕ ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ ȡȠ ȣǺõ ǿǟǼǾȠ ȐƸȘ ÛVS (ȯ/ȯƺȠ

:TS, 6.9 ǒǺŁǺǣ Û**Buffer phosphate** ğǺǺÊǺǒǟ Ǵəǿǟǻ ȯƺŶŢ

ğǺǺÊƺ ȡȠ ȟ 3.55ȘR ƙǅŞǿǼǢŢǟ ǴǢəǺǺǫ ȳƺǢèǺǩƺǴǟ ğǺǺÊƺ ȡȠ ȟ 3.40 āǟǾǺ :*Procedure ǒǟǺǅǅǫǟ*

ǈǅƺǵ ɁŶȝ ȯƺÔȞŶǒ R ȷƺǣǺǑǟ ǼǢÊõǕ ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ ȡȠ ǴǢƺǺõ ǴǢƭõ Ž R ȳƺǺǻƺÔǟ ǴǢəǺǺǫ ƙǅŞǿǼǢŁ

.ǾȠ 1000 ȻǿǼȩ

:TS, 3.4 ǒǺŁǺǣ Û**Buffer phthalate** ğɍǺǯǺǒǟ Ǵəǿǟǻ ȯƺŶŢ

ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ ȡȠ ǾȠ 50 Ž R ȳƺǢèǺǩƺǴǟ ƙǅŞǿǼǢŁ ğɍǺǯ ȡȠ ȟ 2.04 āǟǾǺ :*Procedure ǒǟǺǅǅǫǟ*

ȡȠ ȣǺõ ǿǟǼǾȠ ƵǺǺƚȘ ÛVS (ȯ/ȯƺȠ 0.2) ǾǺǿƺŶõŞǿǼǢŢǟ ȐƥȡȠ ǾȠ 10.40 ȣǺȒǂ ÛR ȷƺǣǺǑǟ ǼǢÊõǕ

.ǾȠ 200 ȻǿǼȩ ǈǅƺǵ ɁŶȝ ȯƺÔȞŶǒ R ȷƺǣǺǑǟ ǼǢÊõǟ ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ

:TS, 3.5 ǒǺŁǺǣ Û**Buffer phthalate** ğɍǺǯǺǒǟ Ǵəǿǟǻ ȯƺŶŢ

ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ ȡȠ ǾȠ 50 Ž R ȳƺǢèǺǩƺǴǟ ƙǅŞǿǼǢŁ ğɍǺǯƺ ȡȠ ȟ 2.04 āǟǾǺ :*Procedure ǒǟǺǅǅǫǟ*

ȡȠ ȣǺõ ǿǟǼǾȠ ƵǺǺƚȘ ÛVS (ȯ/ȯƺȠ 0.2) ǾǺǿƺŶõŞǿǼǢŢǟ ȐƥȡȠ ǾȠ 8.40 ȣǺȒǂ ÛR ȷƺǣǺǑǟ ǼǢÊõǕ

.ǾȠ 200 ȻǿǼȩ ǈǅƺǵ ɁŶȝ ȯƺÔȞŶǒ R ȷƺǣǺǑǟ ǼǢÊõǟ ȖəǺǺǫ ȡȠ ƃǺȽǟ ǒǺƫǟ

.ǴǢõȘǻ ǴǢəǺǢƭǢõ ǴǢȞǅǺȠ ǵǻǺȠ :**Bupivacaine hydrochloride RS** ƙǺõǺǺǢǣƺǴǟ ǼǺǿƺŶõŞǿǼǢŁ

.(54 ǴȞǺÔǟ Û1963 ÛSRIP) $C_4H_{10}O$.[*n*-butanol R] :**1-Butanol R** ȯƺǫǺǩƺǣ - 1

.$(CH_3)_3COH$ Ǖȯȿ – 2 – ȷǺǣȘǺǣ ǾǢǯǢȠ – 2 :***tert*.- Butanol R** ȯƺǫǺǩƺǣ - ,ğǨǨ

.ȷƺŶǟ ǴƸǼȝ ǴŶəǺè ȿǕ ǴǤŶò ǵǻǺȠ :*Description* ƵòƺǛ

.R ƘǫǂǻȘ ÛTS (ȯ/ȟ 750~) ȯƺǫǺǯǺqǟ ÛǒǺƫǟ ȝȠ ǯȘǺȟ :*Miscibility ǴǅǅȘǺƫǟ*

.°ȳ83Ș 81 ǵǿǟǺǵ ǴǅǅǿǴǻ ƙǣ %95 ȡȝ ǾǾǺ ɍ ǺȠ ǺǕǾǂ :*Boiling range ȷǼŶȣǟ ȯǺƒ*

.°ȳ26 – 24 :*Melting range ǿǺŢÔǫɍǟ ȯǺƒ*

.ȯ/ȠŶõ 0.782-0.778 p_{20} :*Mass density ǴŶǫÔǟ ǴƺǺǯõ*

ǵǿǟǺǵ ǴǅǅǿǴǻ Ž ƘǣǺǯǟ ȷǟƺǟ ɁǿǪǵ ȡǺÊȘ ȖəǺȠ ȳǺƥ ɁŶȝ ǺǺǴǂ :*Residue on evaporation ƘǺǫǟǺǣ ǴǟǺƭǯǟ*

.ǾȠ/ȠŶȠ 0.05 ȡȝ ǼǺǺǩ ɍ ǴǟǺǪ ǾǺǪǺ Ǖ°ȳ105

.$C_4H_{11}N$ [illegible] – 1 :**1-Butylamine R** [illegible] - 1

[illegible] :*Description* [illegible]

.R [illegible] (~750 [illegible]) [illegible] :*Miscibility* [illegible]

.°[illegible]78 [illegible] 76 [illegible] %95 [illegible] :*Boiling range* [illegible]

.[illegible] 0.740 [illegible] p_{20} :*Mass density* [illegible]

Determination of water by [illegible] :*Water* [illegible]
.[illegible] 10 [illegible] 5 [illegible] (145 [illegible] 1 [illegible]) "Karl Fischer method

[illegible] TS [illegible] 5 [illegible] 50 [illegible] :*Acid impurities* [illegible]
[illegible] VS ([illegible] 0.1) [illegible]
[illegible]
.[illegible] VS ([illegible] 0.1) [illegible] 1.0 [illegible]

[illegible] %98.0 [illegible] .$(CH_3CO_2)_2Cd,2H_2O$:**Cadmium acetate R** [illegible]
.$(CH_3CO_2)_2Cd, 2H_2O$

.[illegible] :*Description* [illegible]

.[illegible] :*Solubility* [illegible]

~260) [illegible] 25 [illegible] 50 [illegible] 1 [illegible] :*Assay* [illegible]
[illegible] R [illegible] VS ([illegible] 0.1) [illegible] TS ([illegible]
VS ([illegible] 0.1) [illegible] 1 [illegible]
.$(CH_3CO_2)_2$ Cd, $2H_2O$ [illegible] 26.65 [illegible]

.[illegible] :**Caffeine RS** [illegible]

.(59 [illegible] 1963 [illegible] SRIP) $Ca(OH)_2$:**Calcium hydroxide R** [illegible]

:**Calcium hydroxide TS** [illegible]

.R [illegible] :*Procedure* [illegible]

.[illegible] TS [illegible] :*Note* [illegible]

[illegible] :**Carbomer R** [illegible]
[illegible] (%68 - 56) [illegible]
.[illegible] 1 [illegible] °[illegible]80 [illegible] (-COOH) [illegible]

.3 ǦǟǙǻ ȯ/ȟ 10 ȂƎõǠǪǣ ĘŸȞǪÊǹ ǒȦŁǠǣ ŋŸǦȦ :*pH value ǒȦŁȦǦǟǟ ǦȶƎǫ*

Ž ʔȱǦǪÊł .ǿǟǠȶǪèȦǣ ǺȦǠǝǟá ÕȦǠȞǻǪǟǟ 3ŋ ÛǒȦʈǟ ȡŋ Ōŋ 500 Ž ȟ 2.5 Ƀʐʒ ĘŸȞǪÊŋ ǠȒȞł :*Viscosity ǦǞʐşȦŸǟǟ*

ȡŋ Ōŋ1 ÛTS ȯʐǶȦǯȦǗ/ƘȦǒȦǯʐ ȯʐȀʐ ȯʐŸȚ ȡŋ Ōŋ 0.2 ȣȦȒȦ Ż ÛǦȱƎǫá 30 ǥȀŋ °ÿ 0.2 ± 25 ǥǿǟǠǵ ǥǠǞǿá

ȯʐŸȚ ȡŋ ǦȦşȦÊǪŋ ÿʐǞʐǵ ȡŋ ǰȦÂŋ ȯȦȶȞǪèȦǣ ȯȀȞł ÛǺȦǠǝǟá ÕȦǠȞǻǪǟǟ 3ŋş ÛTS ȯʐǶȦǯȦǗ/ȯʐȶƎǫʐŋşȦǣ Ǧǫǿǟ ȯʐŸȚ

Æʑ ɃǾǟǟ ǒȦŁȦǦǟǟ ÒȞȦȦ) .ȄǶȦǞʐǪŋ ȧǿǟȖ ȷʐȯ ȰȮÎǪȦ ʔøǪǵ ǒȦʈǟş TS(ȯ/ȟ 400~) ÿʐȦáʐÔǟǟ ȀƎÊõşǿȀƎȽ

.(ǟǟʐǣ 400 - 300) Pa.s 40 - 30 ȯȀȞŋ ȂȒȞǪÊʈ ǦƎȮƎŋȦȦȦȀǟǟ ǦǞʐşȦŸǟǟ ȷʐȮǩ .(7.8 - 7.3 ȷʐÔȦ ȷȖ

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèʏ ǺȶǝŸŋ ǿʐŸǦǪǟǟ ɃşǠȮǫ ǟʐȯʐŸÊǟǟ ȀȞł :**Cellulose R1** ǟʐȯʐŸÊǟǟ

.ȴ3ȦǶ ÛȒƎǟȖ ȄǶȦǞʐǪŋ ȧʐȞÊŋ :*Description ʐ ȍʐǟǟ*

.ǠǪŋşǠȮǫ 30 ȡŋ ŌǫȖ :*Particle size ǧȦȶƎÊɀǟ ȴǞʐǵ*

(ŌƎŸȣǪǟǟ) ȄƎǦŸǪǟǟ ƘȒƠ Ž ǒȦʈǟ ȡŋ Ōŋ 90 Ž R1 ǟʐȯʐŸÊǟǟ ȡŋ 25 ǦǟǙǻ ȡŋ ĘŸȞǪÊŋ ŌȶȞǪÊł :*Note ǦȚǵŸŋ*

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèǟ ǴǝȦȦȍ ŌǞʐɉ

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèʏ ǺȶǝŸŋ ǟʐȯʐŸÊǟǟ ȀȞł :**Cellulose R2** ǟʐȯʐŸÊǟǟ

.ȴ3ȦǶ ÛȒƎǟȖ ȄǶȦǞʐǪŋ ȧʐȞÊŋ :*Description ʐ ȍʐǟǟ*

.ǠǪŋşǠȮǫ 30 ȡŋ ŌǫȖ :*Particle size ǧȦȶƎÊɀǟ ȴǞʐǵ*

(ŌƎŸȣǪǟǟ) ȄƎǦŸǪǟǟ ƘȒƠ Ž ǒȦʈǟ ȡŋ Ōŋ 100 Ž R2 ǟʐȯʐŸÊǟǟ ȡŋ 15 ǦǟǙǻ ȡŋ ĘŸȞǪÊŋ ŌȶȞǪÊł :*Note ǦȚǵŸŋ*

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèǟ ǴǝȦȦȍ ŌǞʐɉ

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèʏ ǺȶǝŸŋ ǟʐȯʐŸÊǟǟ ȀȞł :**Cellulose R3** ǟʐȯʐŸÊǟǟ

.ȴ3ȦǶ ÛȒƎǟȖ ȄǶȦǞʐǪŋ ȧʐȞÊŋ :*Description ʐ ȍʐǟǟ*

ǥȀì ĘǦǖǪŋ ǠȞÎŋ ʔŸ3 ɃʐǪʒ ɃǾǟǟ (ǠǪŋşǠȮŋ 30 ǧȦȶƎÊɀǟ ȴǞʐǵ şǣ) ǟʐȯʐŸÊǟǟ ÕŸɣ :*Composition ÆƎõȦǪǟǟ*

.ǠǪŋʐǶȦǶ 254 ǦǞʐŋ ȯʐü Ž ʔŸǯȟ

ȄƎǦŸǪǟǟ ƘȒƠ Ž ǒȦʈ ȡŋ Ōŋ 100 Ž R3 ǟʐȯʐŸÊǟǟ ȡŋ ȟ 25 ǦǟǙǻ ȡŋ ĘŸȞǪÊŋ ŌȶȞǪÊł :*Note ǦȚǵŸŋ*

.ǦȱƎǫǠǟǟ ǦȱǦÛǟǟ ǟǟǠÎǪèǟ ǴǝȦȦÔȯ (ŌƎŸȣǪǟǟ)

ÛǧǟǿȀƎȚǟ ǦƎǝȦȦǪ ÿʐƎǫʐŋɉǟ (IV) ÿʐȦǠè ǧȦȦŸè ɃʐǪƠ :**Ceric ammonium sulfate R** ÕȦƘÊǟǟ ÿʐƎǫʐŋȖ ǧȦȦŸè

.$Ce(SO_4)_2,2(NH_4)_2SO_4,2H_2O$ ȡŋ %95.0 ȡ3 ȰȰȦ ɍ Ȧŋ ʔŸ3 $Ce(SO_4)_2,2(NH_4)_2SO_4,2H_2O$

.ƃȦȱǨȦǣ ǠȦȍȖ ȷʐŸǣ ɃǿʐŸǣ ȧʐȞÊŋ şȖ ǠȦȍȖ ȷʐŸǣ ǧǟǿʐŸǣ :*Description ʐ ȍʐǟǟ*

.TS (ȯ/ȟ 750~) ȯʐǶȦǯȦɋǟ Ž ǟǟşǣ Ƙȡ ÜǒȦʈǟ Ž ǒÙǦǣ ǟǟşǣ :*Solubility ǦƎǶȦǣşǾǟǟ*

[illegible] TS ([illegible] 100~) [illegible] 50 [illegible] 1 [illegible] :*Assay* [illegible]
[illegible] 10 [illegible] 0.1 [illegible]
[illegible] 1 [illegible] TS [illegible] – [illegible] VS ([illegible] 0.05) [illegible]
.$Ce(SO_4)_2,2(NH_4)_2SO_4,2H_2O$ [illegible] 63.26 [illegible] VS ([illegible] 0.05) [illegible]

:**Ceric ammonium sulfate/nitric acid TS** [illegible]

130~) [illegible] R [illegible] 5 [illegible] :*Procedure* [illegible]
.[illegible] 100 [illegible] TS ([illegible]

:**VS** ([illegible] **0.1**) **Ceric ammonium sulfate** [illegible]

[illegible] 30 [illegible] 500 [illegible] R [illegible] 65.0 [illegible] :*Procedure* [illegible]
.[illegible] 1000 [illegible] .TS([illegible] 1760~) [illegible]

:[illegible] 0.1 [illegible] :*Method of standardization* [illegible]
[illegible] 15 [illegible] R1 [illegible] 0.2 [illegible]
[illegible] 50 [illegible] .VS ([illegible] 0.2) [illegible]
[illegible] 2.5 [illegible] R [illegible] 0.15 [illegible] TS ([illegible] 100~)
[illegible] .TS [illegible] – [illegible] 0.1 [illegible] TS([illegible] 100~)
.[illegible]

.[illegible] :**Chloramphenicol RS** [illegible]

:**Chloroform, ethanol-free, R** [illegible]

3 [illegible] 20 [illegible] 20 [illegible] R [illegible] 20 [illegible] :*Procedure* [illegible]
[illegible] .[illegible] –20 [illegible]
[illegible] 5 [illegible] R [illegible] 5 [illegible]
.[illegible] 2 [illegible]

[illegible] :**5-Chloro-2-methylaminobenzophenone RS** [illegible] - **4** - [illegible] - **5**
.[illegible]

.$C_6H_5ClN_2O_2$:**2-Chloro-4-nitroaniline R** [illegible] - **4** - [illegible] - **2**

.[illegible] :*Description* [illegible]

[illegible] *Solubility*: [illegible] 750~) [illegible] TS.

[illegible] *Melting range*: 106 – 108°[illegible].

[illegible] *Sulfated ash*: [illegible] 0.5 [illegible].

2-(4-Chloro-3-sulfamoyl)benzoic acid RS [illegible] 2 - (4 - [illegible] - 3 - [illegible]) [illegible]

Chlorphenamine hydrogen maleate RS [illegible]

Chlorpromazine hydrochloride RS [illegible]

Chlortalidone RS [illegible]

Chlortetracycline hydrochloride RS [illegible]

Chromic acid TS [illegible]

[illegible] *Procedure*: [illegible] 84 [illegible] R [illegible] 700 [illegible] 400 [illegible] 1760~) TS.

Chromium trioxide R [illegible] CrO_3 (SRIP [illegible] 1963 [illegible] 68).

Cinchonidine R [illegible] $C_{19}H_{22}N_2O$.

[illegible] *Description*: [illegible]

[illegible] *Solubility*: [illegible] 750~) TS.

[illegible] *Melting temperature*: [illegible] 207°[illegible].

[illegible] *Specific optical rotation*: [illegible] 50 [illegible] 750~) TS -105 to -110° $[\alpha]_D^{20°C}$.

Citrate buffer [illegible] **5.4** **TS**:

[illegible] *Procedure*: [illegible] 2.101 [illegible] R [illegible] 20 [illegible] 100 [illegible] 76.5 [illegible] VS (1 [illegible]) [illegible] 23.5 [illegible] VS(0.1 [illegible]).

Citric acid, copper-free. R [illegible] R [illegible] 0.50 [illegible] 20 [illegible] 100~) TS [illegible] 0.8) TS [illegible] 1 [illegible] 50 [illegible]

.ÄÀöǗ ɹζŏ ǰǪÄÄ

$C_6H_8O_7$ ȡŋ ȟ 20 ǦǽǟÂȩ R ȬÄÄǪĚÊöä Ȑþ ȡŋ ȯζŸȚ Ƀζʒ ؛TS (ȯ ȟ 20) **Citic acid** ȬÄÄǪĚÊöä Ȑþ ȯζŸȚ
.ÄǪö 1 Ž

.ǦĔöȘǻ ǦĔəÅĔȶĔõ ǦĔȞǱÄŋ ǥǻŋ ؛**Cloxacillin sodium RS** ȳζÄǻζÔöä ƙɣĔèÅÊõζŸõ

؛**Cobaltous chloride TS** àζǪöÅǽζȮöä ǼÄøζŸõ ȯζŸȚ

Ȑþ Ōŋ 2.5 ȡŋ ǰÄÂŋ ȡŋ ǦĔζÅõ ǦĔȶõ Ž R àζǪöÅǽζȮöä ǼÄøζŸõ ȡŋ ȟ 6.5 ǡäǾÄ :*Procedure ǒǟÄǱɋǟ*
.Ōŋ 100 ȴǱǵ ʔŸʒ ȯζÔĦʋŸö ǒÅʈä ȡŋ Ōŋ 97.5ȿ TS (ȯ/ȟ 250~) ȬÄøζŸõȿøǼĔȚä

؛**Colbatous thiocyanate TS** àζǨÅǦöζȮöä ǧÅǬÅĔèζĔǬ ȯζŸȚ

ȣÅõ øäǼŌŋ Ž R ȳζĔǬζŋɉä ǧÅǬÅĔèζĔǬ ȡŋ ȟ 4.3ȿ R àζǨÅǦöζȮöä ǼÄøζŸõ ȡŋ ȟ 6.8 ǡäǾÄ :*Procedure ǒǟÄǱɋǟ*
.Ōŋ100 ȴǱǵ ʔŸʒ ȯζÔĦʋŸö ǒÅʈä ȡŋ

.$C_{18}H_{21}NO_3$, H_2O ؛**Codeine R** ƙÄǻζȮöä

.ǦĦəäÀöä ǠǼʒ ǕȐĔǟǗ ɃøζŸǽ ȧζĦÊŋ ȿǗ ǕɹζŸöä ǦɕǼʒ ǧäøζŸǽ :*Description ȤöζǟǞ*
.R ƘǪɉäȿ TS (ȯ/ȟ 750~) ȯζǬÅǮÄɋä Ž ɹÅǽȿǾöä Äǵ ǕöÅʈä Ž ɹÅǽȿǾöä ǴĔĦì :*Solubility ǦĔǬÅǽȿǾöä*
.°ȳ156 ǦǽǟÂȩ :*Melting temperature øÅȚÔǬɼä ǥøÄǵ ǦǱøǻ*

750~) ȯζǬÅǮÄɋä Ž Ōŋ/ȠŸŋ 20 ÂĔõÀǪǽ ȯζŸȚ ŌȶȞǪÊÄ :*Specific optical rotation ɄʒζÄöä ɃÄÔǦöä ÄȿǼǪöä*
.$[\alpha]_D^{20°C}$ -142 to -146º ǕTS (ȯ/ȟ

.ǦĔöȘǻ ǦĔəÅĔȶĔõ ǦĔȞǱÄŋ ǥǻŋ ؛**Colecalciferol RS** ȯȿƘÅĔÊöÅȮĔöζõ

ȡŋ %98.0 ȡʒ ŌǾÄ ɼ Åŋ ʔŸʒ Ƀζǫʒ .$C_4H_6CuO_4$,H_2O ؛**Copper (II) acetate R (II)** âÅĦÄöä ǧÅǪĔèǗ
.$C_4H_6CuO_4$,H_2O

.ȬĔǪèɉä Ȑþ ȬöǾǽ ¢ǦÎÄ ǕǦĦəäÀöä ǠǼʒ ǕȧøàǗ – ÀȒǹǗ ɹζŸǽ ȧζĦÊŋ ȿǗ ǧäøζŸǽ :*Description ȤöζǟǞ*
.ǒÅʈä Ž ǡäȿǽ :*Solubility ǦĔǬÅǽȿǾöä*

ȬĔǪèɉä Ȑþ ȡŋ Ōŋ 2 ȣÅȒÄ ǕöÅʈä ȡŋ Ōŋ 50 Ž ǕǦĔùζǦȒŋ ǦǬȿàζŋ Ǖȟ 0.8 ǡäǾÄ :*Assay ǦÊÄÅŌʈä*
0.1) ȳζÄǻζÔöä ǧÅÄŸèζĔǬ ȯζŸĦŋ øÀĦǪʈä ǻζĔöä ÀÄÅȞÄȿ ǕR ȳζĔèÅǨζǦöä ǼÄǻζÄ ȡŋ ȟ 3ȿ TS (ȯ/ȟ 300~)
ȯζŸȚ ȡŋ ȟ 2 ȣÅȒÄ ǕȤĔÄǹ ȧøàǗ ɹζŏ ʔŌǦÄ ʔøǪǵ ǕÀȞÎȶõ TS ÅÎÄöä ȯζŸȚ ȯÅȶȞǪèÅǽ ǕVS (ȯ/ȯζŋ
ǧÅǬÅĔèζĔǬ ȯζŸȚ ȡŋ Ōŋ 1 Ōõ .ȧøàɉä ɹζŸöä ɄìŸǩ ʔøǪǵ ǥÀÅȞʈä ŌȶȮǪÊǨȿ R ȳζÄǻζÔöä ǧÅǬÅĔèζĔǬ
.$C_4H_6CuO_4$,H_2O ȡŋ ȠŸŋ 19.97 ǜζÅȮÄ VS (ȯ/ȯζŋ 0.1) ȳζÄǻζÔöä

[illegible] **Copper edetate TS** :

[illegible] *Procedure* : [illegible] 2 [illegible] 20 [illegible] 2 [illegible] (II) R [illegible] 2 [illegible]
[illegible] (0.1 [illegible]) VS [illegible] 50 [illegible].

Copper (II) sulfate (II) [illegible] (80 [illegible]) TS: [illegible] (II) R [illegible]
80 [illegible] CuSO4 [illegible] 1 [illegible] (0.5 [illegible]).

Copper (II) sulfate /ammonia TS [illegible] (II) [illegible]:

Procedure : [illegible] 50 [illegible] (II) R [illegible] 1000 [illegible] (~35 [illegible])TS.

Copper (II) sulfate /pyridine TS [illegible] (II) [illegible]:

Procedure : [illegible] 4 [illegible] (II) R [illegible] 90 [illegible] 30 [illegible] R.
Note : [illegible] (II) [illegible]/[illegible].

***o*-Cresol R** [illegible] 2- [illegible] C_7H_8O.

Description : [illegible]
[illegible].

Misciblity : [illegible] (~750 [illegible]) TS [illegible] R [illegible] R [illegible] 50
[illegible].

Mass density p_{20} : [illegible] 1.05 [illegible].

Refractive index n_D^{20} : 1.540 – 1.550.

Boiling temperature : [illegible] 190°[illegible].

Freezing temperature : [illegible] 30.5°[illegible].

Residue on evaporation : [illegible]
[illegible] 105°[illegible] 1.0 [illegible].

Storage : [illegible].

Note : [illegible] – [illegible].

Cyanide/ oxalate/ thiosulfate TS [illegible]:

Procedure : [illegible] 2.0 [illegible] (~100 [illegible]) TS [illegible]: 1.5
[illegible] 15 [illegible] (50 [illegible]) TS [illegible] 45 [illegible] (50 [illegible]) TS [illegible]
[illegible] (60 [illegible]) TS [illegible] 120 [illegible] (320 [illegible]) TS [illegible] 75 [illegible]

.VS (ȯ/ȯǫ 1) ǬǪǿǫǶǬşǿǢǗǡ Ȑ ƥ ȸǫ Ǭǫ 35ş ǕTS (ȯ/ȟ 60) ȳǫǪǻǫǑǚǡ ǧǪǢèǕ
.ȯǪȶǪèɍǡ ǬǦę ǿǿǫǫ TS ǧǪǪèǫǪ/ǧɍǪÊǬǕ/ǢǪǢè ȯǫǙ ǪȒȜ ȷǕ Ǣƶ :Note ǦŢǵŸŋ
Ž ǢèǪǪŋ ǰǪǿǢ ¢ǪŋǬȶȞǪÊǪ :**Cyanoethylmethyl silicone gum R** ǬǢǯǢŋ ǬǢǯǕ ǫǪǢè ȷǫǬǢǢè ŋȶò
.ɃàǪǒǡ ǬǪÊǚǡ āǡǪÎǪèɍǡ

:**Cyanogen bromide TS** ƙǅǫǪǢÊǚǡ ǢǢŋşǪ ȯǫǙ
.ǿǪǺǚǡ ȧǪÎǪèǡ ǢǪǅǪ ǕǪǢǅ ȳǪè :*Caution ǞǾǾ*
ƂǕ TS(ȯ/ȟ 100) ǪǢȭǪǪ ȳǫǢèǪǫǚǡ ǢǢǪǢè ȯǫǙ ȸǫ ǕǢǪƎǪǚǡ ǒǪǪǕ ǕǥǪǕǬǫ ǥǪǕę ȣǪȒǪ :*Procedure ǒǡǞǅǭǡ*
.ȷǫǙǚǡ ɄǪǪƩ ʔǿǪǵ TS1 ȳşƎǚǡ ȯǫǙ
.ȯǪȶǪèɍǡ ǬǦę ǿǿǫǫ TS ƙǅǫǪǢÊǚǡ ǢǢŋşǪ ǪȒȜ ȷǕ Ǣƶ :*Note ǦŢǵŸŋ*
Ǭŋ/ŋǬŋ 2 ǪǢȭǪǪ ȯǫǙ Ȩǚǚ ȸȝ ǥǢì ǢǪǪ ɍ ǪǬǚǚ R ȷǪÊǬȽǫǙǬǢÊǚǡ ǪǢŢɫ :**Cyclohexane R1** ȷǪÊǬȽǫǙǬǢÊǚǡ
ǓǬǦù ȯǪȶȞèǪǪ ǪǬŋǫǪǪ 400 ǅǅǫŋ ȯǫù Ž ȃǪǬǪ ǪŋǢǪȝ VS (ȯ/ȯǫ 0.05) ǬǪǿǫǪǙÊǚǡ Ȑ ƥ Ž R ƙǢǬǚǡ ȸǫ
.ǪǬŋǫǪǪ 365 ǅǅǫŋ ȯǫù Ž ǥǿǪǯǪèǡ ţǪȞìş ȴè 1 ǓǪǺǯǪ

.ǦǢşǻ ǦǢǪǢȶǢȭ ǦǢǅǅǪŋ ǥǻǪŋ :**Dapson RS** ȷǫÊǡǢǚǡ
.ǦǢşǻ ǦǢǪǢȶǢȭ ǦǢǅǅǪŋ ǥǻǪŋ :**Dexamethasone RS** ȷşàǪǯǢŋǪÊǬǪǢǚǡ
.ǦǢşǻ ǦǢǪǢȶǢȭ ǦǢǅǅǪŋ ǥǻǪŋ :**Dexamethasone acetate RS** ȷşàǪǯǢŋǪÊǬǪǢǚǡ ǧǪǢèǕ

ȳǫǢǫŋɉǡ ǧǪǪÊǮ :**Diammonium hydrogen phosphate R** ȳǫǢǫŋɉǡ ǦǢǪǪǪ ƙǅşǿǢǗǡ ǧǪǪÊǮ
.(83 ǦȞǪǑǚǡ Ǖ1963 ǕSRIP) $(NH_4)_2HPO_4$. R

ȯǫǙ :**TS (ȯ ȟ 100) Diammonium hydrogen phosphate** ȳǫǢǫŋɉǡ ǦǢǪǪǪ ƙǅşǿǢǗǡ ǧǪǪÊǮ ȯǫǙ
.ǪǬǬ 1 Ǭȭ Ž $(NH_4)_2HPO_4$ ȸǫ ȟ 100 ǦǡǡǪę Ƀǫȝ R ȳǫǢǫŋɉǡ ǦǢǪǪǪ ƙǅşǿǢǗǡ ǧǪǪÊǫ

.ǦǢşǻ ǦǢǪǢȶǢȭ ǦǢǅǅǪŋ ǥǻǪŋ :**Diazepam RS** ȳǪǦǪàǪǪǢǚǡ

:**Diazobenzenesulfonic acid TS** ǬǢǫǫǪǙè ȸǪǪǿǪşàǪǻ Ȑ ƥ ȯǫǙ
ǬǪǿǫǙǬşǿǢǗǡ Ȑ ƥ ȸǫ Ǭǫ 10 ǿǡǢǬŋ R ǬǢǪǪǙÊǚǡ Ȑ ƥ ȸǫ ȟ 0.9 ƂǕ ȣǪȒǪ :*Procedure ǒǡǞǅǭǡ*
ǿǡǢǬŋ ȯǫǙɉǡ ǡǾŁ ȸǫ Ǭǫ 3 ƂǕ ȣǪȒǪ .Ǭǫ 100 ȴǅǵ ʔǙȝ ȯǫǑȞǙǚ ǒǪţǡ ȸǫ ȣǪȭ ǿǡǢǬŋş TS (ȯ/ȟ 250~)
ȯǫǙ ȸǫ Ǭǫ 20 Ǭǚǡ ǢȞǡ ȣǪȒǪ ǕĘǪǪęǻ 5 ǥǢŋ ȷǙǯǚǡ Ž ǻƎǪ ǕTS(ȯ/ȟ 3) ȳǫǪǻǫǑǚǡ ǨǪǪǬǪ ȯǫǙ ȸǫ Ǭǫ 5
ŞǪǵ Ǣƶ ǕǬŋ 100 ȴǅǵ ʔǙȝ ȯǫǑȞǙǚ ǒǪţǪǡ ǫǪƩ Ǖȷǯǚǡ Ž ǦǢǪǪ ǻƎǪş ǕTS(ȯ/ȟ 3) ȳǫǪǻǫǑǚǡ ǨǪǪǬǪ
.ǡǻǿǪǡ ȯǫǙɉǡ

ثم ǦŐȄęǻ 15 ǼȞǣ ɍǕ ŎȶȞǪÊǺ ɍ ȷǕ ǼƵş ǖǻȴǕàǺù TS ȪȄǷǽǺŸè ȷȟǣşàǺǻǻ Ȕ þ ǺȒƷ ȷǕ ǼƵ :*Note* ǴŢǵŸŋ
.ǨĶȒƠ

:**Diazomethane TS** ȷǺƷȄŋşàǺǺǼǼǟ ȯǽŸȚ

ǦÛèǟǽǣ ǦǟǽȚÊǣ ¢ȒǺȀƠ ǈǪǺ ɃøǺȴǺǷɍǟ ¢ȮȮǺķş ǦǺàǺȣǟǟ ǦǟǺΣǟ Ž ǦǺøǺȴǺǷǟ ǥǻǺŋ ȷǺƷȄŋşàǺǺǼǼǟ :*Caution* ǼǺØƠ
ȷǺƷȄŋşàǺǺǼǼǟ .ţǽǷ ɃǕ ثم ȷǺȄŸȡ ǧǺȄÔǵ şǕ ǥǿşǼŋ ǦȄȴǺȴǽà ŌòǺǺŋ ǧǟǣ ǥǺȚȴǕ ŎȶȞǪÊǺ ɍ .ǦǺÎ Ɩǟ ǳǽÛÊǟǟ
.ǺǼȄȴ ȝǽȚȟ ȷǽǹǟǻ ĶƠ ȜȀθ ȷǕ ǼƵ ǧǺȄŸȶȞǟǟ ŌŏşǦȄȶÊǟǟ ǦȄǟǺȝ ǥǻǺŋ

750~) ȯǽǷǺƷǺȡǟ ثم Ōŋ 10 Ž R ȳǽȄèǺķǽǦǟǟ ǼȄÊŏşǿǼȄȽ ثم ȟ 0.4 ثم ȯǽŸȚ ǺȒƷ :*Procedure* ǿǟǺȴǽȡǟ
ǼȄŋǺǷǽǺŸè - 4 - ثمǺǽǟǽķşàşǺǪǷ - *N* - ŌȄƷȄŋ - *N* ثم ȟ 2.14 ثم ȯǽŸȚ ɃǕ ȣǺȒȴş TS (ȯ/ȟ
ĶŸȮÎķ ǟǣǕ .ǰŸƷǟǟ ȝŸȝ ǼǺƎǪǟǟ ǿǺǺǪǕ R ĸǫɉǟ ثم Ōŋ 30 Ž *N*-mythyl-*N*-nitrosotoluene-4-sulfonamide R
ȯǽŸȚ ȤÛŸǣ ǺÛŎǺ ÛȨǝǺęǻ 5 ǼȞǣ .ǺȚǪǟǟǣȡ TS (ȯ/ȟ 750~) ȯǽǷǺƷǺȡǟ ثم ȣǺŏ ǿǟǼŌŋ ȔŌǽ ȣǺȒȴ ÛǦǟǺèǿ
.ǺǪǟ 1 Ōŏ Ž CH_2N_2 ثم ȟ 10 ǦǟǟǺę ȷǺƷȄŋşàǺǺǼǼǟ ȯǽŸȚ ɃǽƷ .ɄǝǺŋ ȳǺþ ثم Ƀĸǫɉǟǟ ȷǺƷȄŋşàǺǺǼǼǟ
ÛȷǺƷȄŋşàǺǺǼǼǟ ǿǽÎǷ ŌȴǽɉȝǺȠǕ ǧǟǿǟǺȴǽǕ ÛǺȒǺǕ ȳǼǺǪÊķ Ǽę :*Alternative procedures* ǦŸǺǼǦǟǟ ǧǟǿǟǺȴǽȡǟ
.CH_2N_2 ثم ǟǽŸÛţǟ ǺȄŏǺǪǟǟ ȪŸǫ ɃØǟǟ ǰǺǺǟǟ ȯǽŸɉǟ ɃǕ ǦǺǻǿŋ ÛȝǺȠǕ ǦǺǟǼǣ ǻǟǽŋ ȯǺȶȞèǺǣ

.ǦȄǟşǻ ǦȄǝǺȄȶȄŏ ǦȄȞȴǺŋ ǥǻǺŋ :**Diazoxide RS** ǼȄÊŏşǺǺǺǼǟǟ

.$C_8H_{18}O$ ÛDi-*n*-butyl ether ŌȄķǽǣ – *n* – ɄǝǺǪ ĸǫǕ :**Dibutyl ether R** ŌȄķǽǦǟǟ ɄǝǺǪ ĸǫǕ
.ǦȄǝǺŋ ɍ ȷǽȮķ ǺŋǼǺƷ ǺòǽÔǹ ÛǥǺȴǺǪŋ ǧǟǼȄÊŏşĸǣ ŌȄȮÎķ ɃǕ R ŌȄķǽǦǟǟ ɄǝǺǪ ĸǫǕ ǥǻǺŋ ŌȄǪ :*Caution* ǼǺØƠ
.ȷǽŸǟǟ ȻǼƷ ŌǝǺè :*Description* ȤȍǽǟǕ

.R ĸǫɉǟş TS (ȯ/ȟ 750~) ȯǽǷǺƷǺȡǟ ƷŋǕ ǯşǺŋ ŪŏǺţǟ ƷŋǕ ǺȄŸȶƷ ǯşǺŋ ĸȡ :*Miscibility* ǦȄȴşǺţǟ
.°ȳ143 – 140 :*Boiling range* ȷǺȄŸȣǟǟ ȯǺƒ
.ȯ/ŋŸŏ 0.769 p_{20} :*Mass density* ǦŸǪȮǟǟ ǦǽǺƷŏ
.1.344 n_D^{20} :*Refractive index* ɃøǺÊȮǷǟ ǼÊǺţǟ

.$C_{16}H_{22}O_4$ ÛDi-n-butyl phthalate ŌȄķǽǣ - *n* - ɄǝǺǪ ǧɍǺƷǽ :**Dibutyl phthalate R** ŌȄķǽǦǟǟ ɄǝǺǪ ǧɍǺƷǽ
.ĶȽǺǣ ȷǽŸǣ ȷǽŸŋ şǕ ȷǽŸǟǟ ȻǼƷ ÛȣǺò ŌǝǺè :*Description* ȤȍǽǟǕ
.R ĸǫɉǟş TS (ȯ/ȟ 750~) ȯǽǷǺƷǺȡǟ ƷŋǕ ǯşǺŋ ŪŏǺţǟ ƷŋǕ ǺǼȴ ǯǺţǟ ǴȄȟì :*Miscibility* ǦȄȴşǺţǟ
.ȯ/ŋŸŏ 1.048 – 1.043 p_{20} :*Mass density* ǦŸǪȮǟǟ ǦǽǺƷŏ
.1.495 - 1.492 n_D^{20} :*Refractive index* ɃøǺÊȮǷǟ ǼÊǺţǟ
.Ōŋ /ŋŸŋ 0.2 ثمƷ ǼǺÂǺ ɍ :*Sulfated ash* ĶǺŸÊţǟ ǻǺŋǺǟǟ

ÛSRIP) $C_2H_4Cl_2$ Û1,2-Dichloroethane ȷǞǯǕȿǿǫǗõ ɄǝǞǞǭ -2 Û1 :**Dichloroethane R** ȷǞǯǕ ȿǿǫǗõ ɄǝǞǞǭ
.(76 ǦĦĿÔǟ Û1963

Û1963 ÛSRIP) $C_6H_2Cl_3NO$:**2,6-Dichloroquinone chlorimide R** ȷǫǼõȿǿǫǗõ ɄǝǞǞǭ **-6** Û**2** ǼǮȿǿǫǗõ
.(77 ǦĦĿÔǟ

:**2,6-Dichloroquinone chlorimide/ ethanol TS** ȯǫǟǞǯǕ ȷǫǼõȿǿǫǗõ ɄǝǞǞǭ **–6** Û**2** ǼǮȿǿǫǗõ ȯǫǗʈ
ȯǫǟǯqǟ ȡƞ ȣǞõ ǿǟǼȭƞ Ž R ȷǫǼõȿǿǫǗõ ɄǝǞǞǭ-6Û2 ǼǮȿǿǫǗõ ȡƞ ȟ 0.5 ǟǟØ :*Procedure ǿǟǞDZqǟ*
.Ȭƞ 100 ȴDzǵ ʔǗȝ ȯǫÔĦǗ TS(ȯ/ȟ 750~)

.ǦĦȿǻ ǦǝǞȶõ ǦǯDZǞƞ ǥǻƞ :**Dicoumarol RS** ȯȿǿǞƞǫȮǟ ɄǝǞǞǭ

ǦǫȿǞȬʈǟ ǧǞȡȿǞÔʈǟ ȡƞ ǰǞǞƞ ǫȽ .$C_8H_{16}O_3$:**Diethoxytetrahydrofuran R** ȷǟǿǫǫȿǿǼǮȽ Ʉȝǟǿ ɄÊõǫǯǕ ɄǝǞǞǭ
.trans ǦȩȿǞǞʈǟȿ cis

.ȣǞȍ ÛƵǮǞǹ ǞǞȍǕ ȷǫǟ ȿǕ ȷǫǗǟ ǷǼȝ ȬǝǞè :*Description ƶȍǫǟ*

.R Ƙǭɉǟȿ TS (ȯ/ȟ 750~) ȯǫǟǯqǟ ȝƞ ǯȿǞȵ ǗȍǞʈǟ ȝƞ ǞǮǗȶȝ ǯȿǞȵ Ƙȡ :*Miscibility ǦǯDZȿǞʈǟ*

.ȯ/ƞǗõ 0.975 ǦǟǞȩ p_{20} :*Mass density ǦǭȮǟ ǦǫǞǯõ*

.1.418 n_D^{20} :*Refractive index ɃǿǞÊȮqǟ ǼÊǞʈǟ*

:**Diethoxytetrahydrofuran/ acetic acid TS** ȬǮǭèɉǟ Ȑƥ ȷǟǿǫǫȿǿǼǮȽ Ʉȝǟǿ ɄÊõǫǯǕ ɄǝǞǞǭ ȯǫǗʈ
ȬǮǭèɉǟ Ȑƥ ȡƞ ȣǞõ ǿǟǼȭƞ ȝƞ R ȷǟǿǫǫȿǿǼǮȽ Ʉȝǟǿ ɄÊõǫǯǕ ɄǝǞǞǭ ȡƞ Ȭƞ 1 ǯǞǫ :*Procedure ǿǟǞDZqǟ*
.Ȭƞ 100 ȴDzǵ ʔǗȝ ȯǫÔĦǗ R ɄDzǗǯǟ

.$C_4H_{11}N$ ȡƞ %99.5 ȡȝ ȬǞ ɟ Ǟƞ ʔǗȝ ɃǫǬƷ .$C_4H_{11}N$:**Diethylamine R** ƙƞƳǮǯǕ ɄǝǞǞǭ

.ȣǞȍ Ûȷǫǟ ǷǼȝ ȬǝǞè :*Description ƶȍǫǟ*

.ȯ/ƞǗõ 0.704 – 0.702 p_{20} :*Mass density ǦǭȮǟ ǦǫǞǯõ*

.1.386 – 1.384 n_D^{20} :*Reflective index ɃǿǞÊȮqǟ ǼÊǞʈǟ*

VS (ȯ/ȯǫƞ 0.5) ȬǞǿǫǞǗÊǟ Ȑƥ ȡƞ Ȭƞ 50 ƂǕ ÛǦǼüǫǦȒƞ Ǧǫȿàǫƞ Ûȟ 3 ǦǟǞȩ ȣǞȒǞ :*Assay ǦÊǞǞʈǟ*
TS ȯǫǟǯǕ/ ȬǮǯʈǟ ǥǞƥ ȯǫǗʈ ȯǞȶȟǭèǞǟ ÛVS (ȯ/ȯǫƞ 1) ȳǫǞǻǫÔǟ ǼǮÊõȿǿǼǮȽ ȯǫǗĦƞ ȐȶΣǟ ǥǻǞǟ ǞǞȟǩȿ
.$C_4H_{11}N$ ȡƞ ƞǗƞ 73.14 ȕǫǞȮǞ VS (ȯ/ȯǫƞ 0.5) ȬǞǿǫǞǗÊǟ Ȑƥ ȡƞ Ȭƞ 1 Ȯõ .ǞȟÎȶõ

ǥǻƞ :**Diethylcarbamazine dihydrogen cirate RS** ȡǞàǞƞǞǞǞǭǟ ȬǮǯǕ ǦǝǞǞǭ ƙDZȿǿǼƬǟ ǦǝǞǞǭ ǧǟǞǮè
.ǦĦȿǻ ǦǝǞȶõ ǦǯDZǞƞ

[illegible] :**Diethylene glycol succinate R** [illegible]

[illegible].

.(78 [illegible] 1963 SRIP) $C_{55}H_{90}O_{29}$:**Digionin R** [illegible]

:**Digitonin TS** [illegible]

[illegible] TS([illegible] 710) [illegible] R [illegible] 0.10 [illegible] :*Procedure* [illegible]

.[illegible] 10 [illegible]

.[illegible] TS [illegible] :*Note* [illegible]

.[illegible] :**Digitoxin RS** [illegible]

.[illegible] :**Digoxin RS** [illegible]

.C_2H_7N :**Dimethylamine R** [illegible]

.[illegible] :*Description* [illegible]

.R [illegible] TS ([illegible] 750~) [illegible] :*Solubility* [illegible]

[illegible] R [illegible] :**Dimethylamine/ ethanol TS** [illegible]

.C_2H_7N [illegible] 350 [illegible] TS ([illegible] 750~)

[illegible] 50.0 [illegible] 2 [illegible] .TS ([illegible] 750~) [illegible] 10 [illegible] 2 [illegible] :*Assay* [illegible]

([illegible] 0.1) [illegible] VS ([illegible] 0.05) [illegible]

[illegible] VS ([illegible] 0.05) [illegible] 1 [illegible] TS [illegible]

VS [illegible] .C_2H_7N [illegible] 4.508

[illegible] **4-Dimethylaminobenzaldehyde R** [illegible] **- 4**

.(78 [illegible] 1963 SRIP) $C_9H_{11}NO$: **dimethylaminobenzaldehyde R**

:**4-Dimethylaminobenzaldehyde TS1** [illegible] **- 4** [illegible]

[illegible] 65 [illegible] R [illegible] –4 [illegible] 0.125 [illegible] :*Procedure* [illegible]

.TS ([illegible] 25) [illegible] 0.2 [illegible] 35 TS ([illegible] 1760~) [illegible]

.[illegible] TS1 [illegible] –4 [illegible] :*Note* [illegible]

:**4-Dimethylaminobenzaldehyde TS2** [illegible]**-4** [illegible]

[illegible] 80 [illegible] R [illegible] -4 [illegible] 0.80 [illegible] :*Procedure* [illegible]

.TS(ȯ/ȟ 1760) Ȭ̄ʌøɀȦŸȆ̈ö ȀƄ ȡȠ ȟ 20ȿ TS(ȯ/ȟ 750~)

¦**4-Dimethylaminobenzaldehyde TS3** ǼȾȽǼöäƕæɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ - **4** ȯɀŸȚ

ÛTS(ȯ/ȟ 750~) ȯɀɸȦǯʌqǟ ȡȠ Ȭ̄ȠȠ 50 Ž R ǼȾȽǼöäƕæɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ -4 ȡȠ ȟ 0.5 ǟäØʌ :*Procedure* *ŏäǞǱqǟ*

(ȯ/ȟ 750~) ȯɀɸȦǯʌqǟ ȡȠ ȣȦȭ øäǼȬ̄ȠȠ ȤȦƩȿ ÛTS(ȯ/ȟ 420~) Ȭ̄ʌøɀŸȭ̄ȿøǼȾTä ȀƄ ȡȠ Ȭ̄ȠȠ 1 ȣȦȒʌ

.Ȭ̄ȠȠ 100 ȴǱzǵ ɂŸȝ ȯɀȎȞŸö

¦**4-Dimethylaminobenzaldehyde TS4** ǼȾȽǼöäƕæɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ - **4** ȯɀŸȚ

ȀƄ ȡȠ Ȭ̄ȠȠ 5 ȡȠ ǰʌȂȠ Ž R ǼȾȽǼöäƕæɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ -4 ȡȠ ȟ 2 ǟäØʌ :*Procedure* *ŏäǞǱqǟ*

.R ȸǱzŸǯöä Ȭ̄ȾǪȾȅɉä ȀƄ ȡȠ Ȭ̄ȠȠ 95ȿ TS(ȯ/ȟ 420~) Ȭ̄ʌøɀŸȭ̄ȿøǼȾTä

.$C_{11}H_{13}NO$ ¦**4-Dimethylaminocinnamaldehyde R** ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ - **4**

.ǥȂȾư ǦȞəäǿ ǕɃøɀŸæ ȧɀȞȆȠ ȿǕ ÛǦȾöȦȬ̈ǨȦæ ǧäøɀŸæ :*Description* *Ȥȍɀöä*

ȬȾŸȩ ÛTS(ȯ/ȟ 70~) Ȭ̄ʌøɀŸȭ̄ȿøǼȾTä ȀƄ Ž ȷȦæȿØöä Ȧǵ ǕöȦȶä Ž ȾȾŸȶȝ ǟäȿæ Ƙȡ :*Solubility* *ǦǪɉȦæȿØöä*

.Ƙǭɉäȿ TS (ȯ/ȟ 750~) ȯɀɸȦǯʌqǟ Ž ȷȦæȿØöä

¦**4-Dimethylaminocinnamaldehyde TS1** ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ - **4** ȯɀŸȚ

ȀƄ ȡȠ Ȭ̄ȠȠ 100 ȡȠ ǰʌȂȠ Ž R ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ -4 ȡȠ ȟ 2 ǟäØʌ :*Procedure* *ŏäǞǱqǟ*

.TS (ȯ/ȟ 750~) ȯɀɸȦǯʌqǟ ȡȠ Ȭ̄ȠȠ 100ȿ VS (ȯ/ȯɀȠ 5) Ȭ̄ʌøɀŸȭ̄ȿøǼȾTä

.°ȳo ǦäȦȩ ǥøäȦǵ ǦǱøǻ Ž ȯɀŸɉä ȷȂƩ :*Storage* *ȡʌȦǼǪöä*

¦**4-Dimethylaminocinnamaldehyde TS2** ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ - **4** ȯɀŸȚ

ȯɀɸȦǯʌqǟ ȡȠ ȣȦȭ øäǼȬ̄ȠȠ TS1 ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ – 4 ȡȠ Ȭ̄ȠȠ 20 ȤȦǺȽ :*Procedure* *ŏäǞǱqǟ*

.Ȭ̄ȠȠ 100 ȴǱzǵ ɂŸȝ ȯɀȎȞŸö TS(ȯ/ȟ 750~)

.ȾǱzäȦù TS2 ǼȾȽǼöȦȠȦǼȅɀǼȠǖ ȬȾǯȠ ȸəȦǻǭ – 4 ȯɀŸȚ ȦȒȜ ȷǕ ǼƵ :*Note* *ǦȚǵŸȠ*

.(79 ǦȞȦȎöä Û1963 ÛSRIP) $C_6H_4N_2O_4$ ¦**Dinitrobenzene R** ȡʌȂøȦǤöä ȿȀǬǭ ȸəȦǻǭ

¦**Dinitrobenzene/ ethanol TS** ȯɀɸȦǯʌǕ ȡʌƕǤöä ȿȀǬǭ ȸəȦǻǭ ȯɀŸȚ

ȯɀȎȞŸö TS(ȯ/ȟ 750~) ȯɀɸȦǯʌqǟ ȡȠ ȣȦȭ øäǼȬ̄ȠȠ Ž R ȡʌƕǤöäȿȀǬǭ ȸəȦǻǭ ȡȠ ȟ 1 ǟäØʌ :*Procedure* *ŏäǞǱqǟ*

.Ȭ̄ȠȠ 100 ȴǱzǵ ɂŸȝ

.$C_{26}H_{42}O_4$ ¦**Dinonyl phthtalate R** ȬȾǭɀɸ ȸəȦǻǭ ǧɎȦǯȥ

.ƘȽȦæ ȦȂȍǕ ƂǕ ȷɀŸä ƇǼȝ ÛȝȂȯ ȬəȦȅ :*Description* *Ȥȍɀöä*

[illegible] 0.98 – 0.97 p_{20} *:Mass density* [illegible]

[illegible] 1.489 – 1.482 n_D^{20} *:Refractive index* [illegible]

Determination of water by [illegible] *:Water* [illegible] 1.0 [illegible] 2 [illegible] (145 [illegible] 1 [illegible]) "the Karl Fischer method [illegible]

[illegible] 5.0 [illegible] 25 [illegible] 1 [illegible] *:Acidity* [illegible] 0.3 [illegible] TS [illegible] 5 [illegible] (0.5 [illegible]) VS ([illegible] 0.1) [illegible]

(81 [illegible] 1963 SRIP) $C_{12}H_{11}N$:**Diphenylamine R** [illegible]

[illegible] :**Disodium chromotropate R** [illegible]

$C_{10}H_6Na_2O_8S_2,2H_2O$: chromotropic acid sodium R

[illegible] *:Description* [illegible]

TS ([illegible] 750~) [illegible] *:Solubility* [illegible]

[illegible] 1 [illegible] 10 [illegible] 2 [illegible] 0.5 [illegible] *:Identification* [illegible] TS ([illegible] 25) [illegible]

4 TS ([illegible] 1760~) [illegible] 9 [illegible] 10 [illegible] 5 [illegible] *:Sensitivity* [illegible] 1000 [illegible] TS [illegible] 0.5 [illegible] 0.2 [illegible] 5 [illegible] 30 [illegible]

[illegible] :**TS** ([illegible] **10**) **Disodium chromotropate** [illegible] 1 [illegible] $C_{10}H_6Na_2O_8S_2$ [illegible] 9.5 [illegible] R [illegible]

[illegible] R [illegible] :**TS** ([illegible] **50**) **Disodium edetate TS** [illegible] 1 [illegible] $C_{10}H_{14}N_2Na_2O_8$ [illegible] 50 [illegible]

[illegible] R [illegible] :**VS** ([illegible] **0.1**) **Disodium edetate** [illegible] 1000 [illegible] $C_{10}H_{14}N_2Na_2O_8$ [illegible] 33.42 [illegible]

[illegible] :*Method of standardization* [illegible]

.179 ǦĦĄÔöä Û1ÆŸÖä Ž VS (ò/òǫ 0.05) ÿǫÅåǫÔöä ǦĘəĄĄǭ ǥĄǬĄÆĄǕ òǫŸȚ ǰäǫĄȝ ǨƠ ȣǫòǫ ǫȽ ĄŧȭȲ ÛɃǕ

R ÿǫÅåǫÔöä ǥĄĄÊǫ **Disodium hydrogen phosphate R** ÿǫÅåǫÔöä ǦĘəĄĄǭ ƙDZşøÆĘȚä ǥĄĄÊǫ

.(192 ǦĦĄÔöä Û1963 ÛSRIP) $Na_2HPO_4,12H_2O$ ⁝ **Sodium Phosphate**

ǥĄĄÊǫ òǫŸȚ ⁝**TS** (ò ȟ **40**) **Disodium hydrogen phosphate** ÿǫÅåǫÔöä ǦĘəĄĄǭ ƙDZşøÆĘȚä ǥĄĄÊǫ òǫŸȚ

.ĄǬö 1 ŐȭŽ Na_2HPO_4 ȸǫ ȟ 40 ǦäĄę Ƀǫȝ R ÿǫÅåǫÔöä ǦĘəĄĄǭ ƙDZşøÆĘȚä

.(83 ǦĦĄÔöä Û1963 ÛSRIP) $C_{13}H_{12}N_4S$ ⁝**Dithizone R** ǰşÂĘǯÅÆöä

ǦĘĦDZĄǫ ǥåĄǫ ⁝**4-Epianhydrotetracycline hydrochloride RS** ƙŸÒĘèäĄǬƙşøÆĘŒĄ ɄøǦĄǕ - **4** ÆÅøǫŸȭşøÆĘȽ

.ǦĘöşå ǦĘəĄĘŧĘȭ

ǫȽ ĄŧȭR ȸĄĄĄĘĄĘäǕ ƙDZşøÆĘȽ ǥäĄùĄù ⁝**Epinephrine hydrogen tartrate R** ȸĄĄĄĘĄĘäǕ ƙDZşøÆĘȽ ǥäĄùĄù

òǫĄĄƘĸøĄĄĘö āĄĘȡ ŐDZȷ ɃĄǬöä øĄǦǬǹŗä ɃǕ ÆĘDZǬÊĸ ɄøǬöäÛ122 ǦĦĄÔöä Û2 ÆŸÖä Ž ǥåşĄǫǧä Ž ȣǫòǫ

.levarterenol

ȸǫ ÿǫDzǥ 4 ǯÂǬ .(88 ǦĦĄÔöä Û1 ÆŸÖä) òäĄĄöä ɄęøǫöäāäĄÎǬèŗä ĘǦÛł :*Levarterenol òǫĄĄƘĸøĄĄĘŸöä*

ŐÔĄĄĸ ʔøǬǥ ōĄǬŀş ȐǺł ÛöĄţä ȸǫ ÿǫDzǥ 5ş ÛR ɄDzŸǯöä ŌĘǬĘèȷä Ȑ ƥ ȸǫ ĄŧDzǥ 1ş ÛR òǫǬĄĸǫä–1

ȸǫ ĄǬöşĄÒǫ 20 ǦęøǫöäʔŸȝ ĘǦÛł .ōĄĦǬǫ øǫÛȭ ǦĄǫŸĦöä ǦŐǦÛöäş ǨäĄǭ øǫÛȭ ʔŸĄÊöä ǦŐǦÛöä ŐŧĦǬÊĸ .ǰĄǬŐǦÛöä

æĄĄş ÛǦęøǫöä ȤĄDzƙ ÛǥĄȝĄè 5 ǥÆǫ øǫÛł ÛR ȸĄĄĄĘĄĘäǕ ƙDZşøÆĘȽ ǥäĄùĄù ȸǫ Őǫ/ȠŸǫ 50 Ƀǫȝ òǫŸȚ

TS Û8 ŏĄȽĄæ ÛǥäøǫǦöä ǦəøäåŽ āäØţä Őǫ /ȠŸǫ 4.4 ĄĘȭĄǬæ R ÿǫĘèĄĸǫǦöä ÆĘǬĄĘè ɃƘǫ ȸǫ ĄDZäĄù ĄȐȚ òǫŸĦǫ

.(ɃåøşĄƥǕ) ɄŸĄǬĄę ǰǫö ǥäæ ÛǥÆǥäş ǦĦȭæĄȚȚĸ Û¢ÊĄǬ ŏĄȽĄǦöä ŌŸǬ ʔĄǹǕ ǦəøäåŐŧĦǬÊĸ Æę şǕ

.ǦĘöşå ǦĘəĄĘŧĘȭ ǦĘĦDZĄǫ ǥåĄǫ ⁝**4-Epitetracycline hydrochloride RS** ƙŸÒĘèäĄǬĸ ɄøǦĄǕ ÆĄøǫŸȭşøÆĘȽ - **4**

.ǦĘöşå ǦĘəĄĘŧĘȭ ǦĘĦDZĄǫ ǥåĄǫ ⁝**Ergometrine hydrogen maleate RS** ƙǫĄĸǫȡøȷä ƙDZşøÆĘȽ ǥĄĘöĄǫ

.ǦĘöşå ǦĘəĄĘŧĘȭ ǦĘĦDZĄǫ ǥåĄǫ ⁝**Ergotamine tartrate RS** ƙǫĄĸǫȡøȷä ǥäĄùĄù

.ǦĘöşå ǦĘəĄĘŧĘȭ ǦĘĦDZĄǫ ǥåĄǫ ⁝**Estrone RS** ǰşĄǬÊÅɋä

.ǦĘöşå ǦĘəĄĘŧĘȭ ǦĘĦDZĄǫ ǥåĄǫ ⁝**Ethambutol hydrochloride RS** òǫĸǫǦǫĄǯÅɋä ÆÅøǫŸȭşøÆĘȽ

⁝**Ethanol, neutralized TS** òÆĦǬÊţä ÛòǫǬĄǯÅɋä òǫŸȚ

òǫĄĘǫ òǫŸȚ ȸǫ Őǫ 0.5 øäÆŐǫ TS (ò/ȟ750~) òǫǬĄǯÅɋä ȸǫ ǦǦèĄĄǫ ǦĘŧȭ ɃǕ ȣĄȐĄ :*Procedure öäĄDZǫɋä*

(ò/òǫ 0.02) ǥĄǬǫæĄÒöä ȸǫ ɃĄȿä ÿǫÅåǫÔöä ÆĘÊȭşøÆĘȽ òǫŸȚ ȸǫ ȣĄȭ øäÆŐǫ ÙŐǫş TS òǫǬĄǯÅǕ/ƙĄöĄǯǫ

.ǨȽĄæ ɄŸĄǬĄę ǰǫö ʔŸȝ òǫÔĦŸö VS (ò/òǫ 0.1) şǕ VS

[illegible] *Note:* [illegible] TS [illegible].

[illegible] TS (~750 [illegible]) **Ethanol, aldehyde-free** [illegible] (**95** [illegible]) **R** : (SRIP 1963 [illegible] 84).

[illegible] **Ethanol** (**675~** [illegible]) **TS**: [illegible] 842 [illegible] TS (~750 [illegible]) [illegible] 1000 [illegible].

[illegible] **Ethanol** (**600~** [illegible]) **TS**: [illegible] 735 [illegible] TS (~750 [illegible]) [illegible] 1000 [illegible].

[illegible] **Ethinylestradiol RS**: [illegible].

[illegible] **Ethosuximide RS**: [illegible].

[illegible] **Ethylenediamine R**: $C_2H_8N_2$.

Description: [illegible].

Miscibility: [illegible] TS (~750 [illegible]) [illegible] R.

Boiling temperature: 116 [illegible].

Mass density: p_{20} 0.898 [illegible].

Storage: [illegible].

[illegible] **Ethyl iodide R**: C_2H_5I (SRIP 1963 [illegible] 87).

[illegible] **Ethylmethylketone R**: C_4H_8O.

Description: [illegible].

Miscibility: [illegible] TS (~750 [illegible]) [illegible] R [illegible] R.

Boiling range: 79 – 80 [illegible].

Mass density: p_{20} 0.805 [illegible].

[illegible] **Ferric ammonium sulfate TS1**:

Procedure: [illegible] 0.2 [illegible] R [illegible] 50 [illegible] 6 [illegible] TS (~1000 [illegible]) [illegible] 100 [illegible].

[illegible] **Ferric ammonium suflate TS2**

Procedure: [illegible] 8.3 [illegible] R [illegible]

.ǾȠ 1000 ǋǱǵ ɁǛȝ ȯɀȎǗǛ VS (ȯ/ȯɀȠ 0.25)

ǧǺȶȆǭ ǋǱǵ ȝȠ ȺȁȈ ȁǻÎȅȓ Ž ȯǺȶǶȅǛ ǴȅǺȠ ǴǱǿǻ ؛**Firebrick, pink, R** ÛɄǛǺȁ ÛɃǿȁǵ ȀǱǓ

.ȀȠȘȀȮȠ 250 – 180 ǴȁȀ ȸȠ

.ǴȅȘǻ ǴǝǺȶȭ ǴǶǱȀȠ ǵǻǺȠ ؛**Fluphenazine decanoate RS** ȸȁǺɀǛǗ ǧɀǺȮǻ

.ǴȅȘǻ ǴǝǺȶȭ ǴǶǱȀȠ ǵǻǺȠ ؛**Fluphenazine enantate RS** ȸȁǺɀǛǗ ǧǺȁǺǓ

.ǴȅȘǻ ǴǝǺȶȭ ǴǶǱȀȠ ǵǻǺȠ ؛**Fluphenazine hydrochloride RS** ȸȁǺɀǛǗ ǼǿɀǛȭȘǿǼǢ

.ǴȅȘǻ ǴǝǺȶȭ ǴǶǱȀȠ ǵǻǺȠ ؛**Folic acid RS** ȭǺɀǗ Ȁƥ

.(91 ǴɄȎǗ Û1963 ÛSRIP) ؛ **R** ǼǢǼǺȠǿɀɀ **Formalehyde TS** ǼǢǼǺȠǿɀɀ ȯɀǛȚ

؛**Formaldehyde /sulfuric acid TS** ȭǿɀǛȆǗ Ȁƥ ǼǢǼǺȠǿɀɀ ȯɀǛȚ

ȸȠ ǾȠ 0.2 ǿǼȠ TS (ȯ/ȟ 1760~) ȭǿɀǛȆǗ Ȁƥ ȯɀǛȚ ȸȠ ǾȠ 10 ȻǕ ȣǺȒ :*Procedure* *ǿȀǱɋ*

.TS ǼǢǼǺȠǿɀɀ ȯɀǛȚ

.ǮȒǾ ǼǶ ȀǮ 1 ȯǛȵ ǾȶǶȆ :*Shelf-life* *ȸȀǺǗ ȀȶȜ*

.(92 ǴɄȎǗ Û1963 ÛSRIP) CH_3NO ؛**Formamide R** ǼȠǺȠǿɀɀ

ȸȜ ǾǾ ɍ Ǻȵ ɁǛȝ ɃɀȜ .*d*~1.22 ÛCH_2O_2 ؛**Formic acid, anhydrous, R** ÛɄǺȠǛǗ ÛȭȠǿɀǗ Ȁƥ

. CH_2O_2 ȸȠ %98 0

.ǴȜǻɍ ÛǴɄǗ ÜȷɀǛǗ ǶǼȜ ǾǺȅ :*Description* *ǮȍɀǗ*

.TS (ȯ/ȟ 750~) ȯɀǺǯȁȘ ǿǺȶ ȝȠ ǯȘȀȠ :*Miscibility* *ǴǱȘȀȶ*

ǿǺǴȵɍǻ" ȷǻɀȝ ǨǾ ȣɀǿɀȠ ɀȽ Ǻȶȭ ǾȶǶǗ ǾȶǾȘ ǿǺȶǻ Ǿȵ 15 ȻǕ Ǿȵ 1 ǮǺƩ :*Chlorides* *ǧǻǼǿɀǾǗ*

ɄǺȠǛǗ ȭȠǿɀǗ Ȁƥ ɃɀȜ .(124 ǴɄȎǗ Û1 ǼǛǾ) "Limit test for chlorides ǧǻǼǿɀǾǗ ǾǱȷ ȺǼƩ

.ȟ/ȠǛ 0.50 ȸȜ ǼȀȀ ɍ Ǻȵ ɁǛȝ R

ǿǺǴȵɍǻ" ȷǻɀȝ ǨǾ ȣɀǿɀȠ ɀȽ Ǻȶȭ ǾȶǶǗ ǾȶǾȘ ǿǺȶǻ Ǿȵ 15 ȻǕ Ǿȵ 0.5 ǮǺǺȽ :*Sulfates* *ǧǺǛȆǗ*

R ɄǺȠǛǗ ȭȠǿɀǗ Ȁƥ ɃɀȜ .(125 ǴɄȎǗ Û1 ǼǛǾ) "Limit test for sulfates ǧǺǛȆǗ ǾǱȷ ȺǼƩ

.ȟ/ȠǛ 1.5 ȸȜ ǼȀȀ ɍ Ǻȵ ɁǛȝ

ǴǱǿǻ Ž ǨǺǯǗ ȷȁɀǗ ɁǿȅǴ ǮǺȥȘ ɄǺȠ ǛǺƥ ɁǛȝ ȀǺǴ :*Residue on evaporation* *ǨǺǴǗ ȸȠ ǴǺȶǯǗ*

.ǴǺȶǯǗ ȸȠ ȟ/ȠǛ 0.5 ȸȜ ǼȀȀ ɍ Ǻȵ ȭȀȅ Ü°ǛƖ105 ǵǿȀǵ

ǾǺȅ ȸȠ Ǿȵ 1 ǴȁȀ ÛǾǺȶ ȸȠ Ǿȵ 10 ǴȁȀ ɃɀǾ ȷȁɀǗ ǴȀȀȠ ǴǛǱɀǵ ȻǕ ǴȜȀȆ ȣǺȒ :*Assay* *ǴȆǼǾȶ*

ğ ÀǿǬǣÀ̀Ȯöä ȸȠ ƃÀ̇ʅ ä ÿǬÀ̂áǬÔöä ǼǢÊõşǿǼǢŁ ȯǬŸƮ ǦÛèǟǬǣ ÀÀǨÀş ÛȯÀ̇ţä ȸȠ Ōȵ 50 øǣ ǮÀ̇Ƹ .ɹäǬÀş ÛǿÀ̇Ǭ̀ǹɼä ǼǢÊõşǿǼǢŁ ȯǬŸƮ ȸȠ Ōȵ 1 Ōõ .ÀǨÎŧõ TS ȯǬǿÀ̇ǯÀÙ/ƙÀ̇öÀǯǬ ȯǬǼǬ ȯǬŸƮ ȯÀ̇ŧǨǪèÀ̇ǣ ÛVS (ȯ/ȯǬȠ 1) .CH_2O_2 ȸȠ ȠŸȠ 46.03 ǜǬÀ̇Ȯ/ VS (ȯ/ȯǬȠ 1) ğÀ̇ǿǬǣÀ̀Ȯöä ȸȠ ƃÀ̇ʅä ÿǬÀ̂áǬÔöä

rosaniline ƙŸǢǿÀ̇èşÀ̀öä ǼÀǿǬŸõşǿǼǢŁ ȸȠ ǰÀÂȠ R âÀ̇èÛ ÛÀǪǼǭÀ̇ȵ ¦**Fuchsin, basic R** Û â À̇èÛ ÛƙÊõǬÀ̇öä Pararosaniline ƙŸǢǿÀ̇èşǿäǿÀ̇Ǧöä ǼÀǿǬŸõşǿǼǢŁş Û$(H_2NC_6H_4)_2C$: $C_6H_3(CH_3)$: $NH_2^+Cl^-$ Ûhydrochloride .$(H_2NC_6H_4)_2C$: C_6H_4: $NH_2^+Cl^-$ hydrochloride

.ğÀ̀Ȓʅä ƃÛ äǿÀ̇ȑ – ɃÂǿşÀ̀ǣ ĘÀÀ̀ǣ ÛɹÀ̇ǨţȜȠ ÛǦÀǿǬŸǣ ğÀ̇ǬǼǨ şÛ ğäǿǬŸǣ :*Description* *Ǯöǭöä*

.R ŌǢȠɉä ȯǬǶõş ÛTS (ȯ/ȟ 750~) ȯǬǿÀ̇ǯÀǪǣş ŏÀ̇ţä Ž äȧşǣ :*Solubility* *ǦǢǿÀ̇ǣşǾöä*

0.10 ȸȠ À̀ǯõÛ ǼŌÀÀ ɼ Ü°ÿ105 ǥǿäÀ̀ǵ ǦǱǿá Ž ƘǣÀ̇ǯöä ɹäǬöä ʔøǪǵ ǮÀ̇ǱȽ :*Loss on drying* *ǮǼÀ̇ǱǪöÀ̇ǣ ǼŌÀöä* .ȟ/ȟ

ǼÀÂÀ ɼ ÜTS (ȯ/ȟ 1760~) ŌÀǿǬÀ̇ŸÊöä ȒƥȯǬŸƮ ȸȠ Ōȵ 0.5 ȜȠ ȟ 1 ŌǨÎɫ :*Sulfated ash* *ƘÀ̇ŸÊţä áÀ̇ȠÀ̇öä* .ȟ/ȠŸȠ 3.0 ȸȜ

¦**Fuchsin TS** ƙÊõǬÀ̇öä ȯǬŸƮ

áȜǢö õÀ̀ǪÀ .ŏÀ̇ţä ȸȠ Ōȵ 60 Ž TS (ȯ/ȟ 1760~) õǿǬÀ̇ŸÊöä Ȓƥ ȸȠ Ōȵ 40 ǿǾɯ ǼÔÀ :*Procedure* *ŏäÀ̇ǱǬǭä* –ÀÀöÛ ɹǬö ǿǬÛǪÀ .ǿäÀ̀ŌǪèŸö õÀ̀Ǫş Ōȵ 200 ƃÛ ŏÀ̇ţÀ̇ǣ ǮÀ̇ǺȽ .R âÀ̇èɉä ƙÊõǬÀ̇öä ȯǬŸƮ ȸȠ Ōȵ 100 ȣÀ̇Ȓɫş .ɄǱǬŸǯöä ŌǢǪǢèɉä Ȓƥ ȸȠ ȿÀ̇ÊȠ ǈǱɯ ǥÀ̀ïÀ̇ǦȠ ȯÀ̇ŧǨǪèɼä ŌǦȩ ȯǬŸɫä ǮÀ̇ǺȽ .ƃÀ̇ŌǨÀǣ

.ǦǢöşá ǦǢəÀ̇ǢŧǢõ ǦǢǨǱǮÀ̀ȵ ǥáÀ̇ȵ ¦**Furosemide RS** ǼǢŧǢèşǿǬÀ̇öä

.ǦǢöşá ǦǢəÀ̇ǢŧǢõ ǦǢǨǱǮÀ̀ȵ ǥáÀ̇ȵ ¦**Griseofulvin RS** ƙÀ̇öǬǬşÂÀÀ̀ȣöä

.ǦǢöşá ǦǢəÀ̇ǢŧǢõ ǦǢǨǱǮÀ̀ȵ ǥáÀ̇ȵ ¦**Haloperidol RS** ȯşǼÀƘǣǬöÀ̇Ł

.C_6H_{14} Û*n*-Hexane ¦**Hexane R** ɹÀ̇ÊȮŁ

.ɹǬŸöä ǢǼȜ ÛǯäÀ̀ǱǬǿ ÛȯÀ̇ǨǪïɼä ȜÀÀ̀è ŌəÀ̇è :*Description* *Ǯöǭöä*

.°ÿ69.5ş 67.5 ƙǣ °ÿ1 ȸȠ ȯÀ̇ƒ ȧǬǬ ŌȠÀ̇õ ŌȮÎǣ À̀ÛŌÀ :*Boiling range* *ɹÀ̇ǼŸȣöä ȯÀ̇ƒ*

.ȯ/ȠŸõ 0.659 – 0.658 p_{20} :*Mass density* *ǦŸǪȮöä ǦǬÀ̇ǯõ*

.1.375 – 1.374 n_D^{20} :*Refractive index* *ɃǿÀ̇ÊȮǿǭä ǼÊÀ̇ţä*

.N_2H_4,H_2O ȸȠ %98.0 ȸȜ ŌŌÀ ɼ À̇ȵ ʔŸȜ ɃǬǪȜ .N_2H_4,H_2O ¦**Hydrazine hydrate R** ȸÀäǿǼǢTä ğäǿǼǢŁ

.ȣÀ̇ö ÛɹǬŸöä ǢǼȜ ŌəÀ̇è :*Description* *Ǯöǭöä*

.ŏǺţ̂ 3ŋ ǯşÂȟ *:Miscibility ǦĒDZşÂţ̂*

5.0 ȸ3 ǼÂÂǩ ɍ ǦöǺɋ ȭÂ0Â ÜꞸǝǺŋ ÿǺþ ʡŸ3 ȣǺÂƨâ ʡøǪǵ ÀǺGÂ *:Residue on evaporation ǨǺGǪöâ ȸŋ ǦöǺŧǯöâ*
.ȟ/ŋŸŋ

420~) ȭÂøzŸȭşøǼĒTâ ȐŧɯÂ ȯzŸƚâ äǾȽ ȸŋ Ōŋ 20 ȯǼȞǪÊÂ ÛöǺţǺǝ Ōŋ 200 ƂǓ ȟ 1 ȤǺƩ *:Assay ǦÊÂǺŌţ̂*
ȯzŸĦŋ ÀÂǺȞɫ ÛTS (ȯ/ȟ 100) ÿzĒèǺǩzGöâ ǼĒɸǺĒè ȯzŸȚ ȸŋ Ōŋ 5 ȣǺȒÂ .ǥǻÂÂǝ Ōŋ 10 ȣǺȒÂş TS (ȯ/ȟ
ǺÎǺöâ ȯzŸȚ ȣǺȒÂ ÛȞǪȽǺǝ ȡɍşǓ ŌÒÎǪÂ ɃǾöâ ꞸøǺGöâ ȷzŸöâ ǴGÔÂ ʡøǪǵ VS (ȯ/ȯzŋ 0.05) ÿzĒèǺǩzGöâ ğâǻzÂ
VS (ȯ/ȯzŋ 0.05) ÿzĒèǺǩzGöâ ğâǻzÂ ȯzŸȚ ȸŋ Ōŋ 1 Ōȭ .ȧǿäɉâ ȷzŸöâ ꞸÂǪƩ ʡøǪǵ ǥÀǺȞţâ 3âǺǪǩş ÛTS
.N_2H_4,H_2O ȸŋ ŋŸŋ 2.503 ȕzǺÒÂ

ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ ǼĒDZǪÊÂ :**FeTS** (ȯ ȟ **250~**) **Hydrochloric acid** ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ
Ōŋ 40 ȣǺȒÂ ÛꞸǝǺŋ ÿǺþ ʡŸ3 ȞGÂÀŌǩ ȣǺÂƨâ ʡøǪǵ Ōŋ 5 ÀǺGɫ :ƂǺǪöâ ŽǺȓɋâ ǿǺGǪȠɍâ ƂǓ TS (ȯ/ȟ 250~)
Ûǯǻƨ ÜR ȭĒǪĒèÜzǪǝǺȭǨţâ Ȑþ ȸŋ ȷǺǩǺÛęş ÛFeTS (ȯ/ȟ 180) ȭÂÀǪĒÊöâ Ȑþ ȯzŸȚ ȸŋ Ōŋ 2 ÛöǺţâ ȸŋ
.ꞸŸǺɸÀę ȷzȯ ŌÒÎǪÂ ɍ ÜöǺţǺǝ Ōŋ 50 ƂǓ ȤǺƩş ÛFeTS (ȯ/ȟ 100~) ǺĒɸzŋɉâ ȯzŸĦŋ ȞÂzŸę ŌȞDzɫ

:**Hydrochloric acid, brominated, AsTS** ÛÿşꞮöǺǝ žǺȞţâ ÛȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ
ȸŋ Ōŋ 1 ǿâǼŌŋ AsTS (ȯ/ȟ 250~) ȭÂøzŸȭşøǼĒTâ Ȑþ ȸŋ Ōŋ 100 ƂǓ ȣǺȒɫ *:Procedure ŏâÀDZɋ̂*
.AsTS ÿşꞮöâ ȯzŸȚ

ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ ȤǺƩ :**VS** (ȯ ȯzŋ **5**) **Hydrochloric acid** ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ
.Ōŋ 1000 Ž HCl ȸŋ ȟ 182.35 Ƀz3 ʡøǪǵ ÛöǺţǺǝ ÛTS (ȯ/ȟ 250~)

ǦŌÂÀÛöâ ţǺGǩǺǝ ȯzŸĦŧŸö ĘĒęǼöâ ÂĒȭÀǪöâ ȸŋ ĘŌĦǪöâ ʔÀƶ *:Method of standardization ȄĒĒŌǪöâ ǦŌÂÀü*
.200 ǦĦǺÔöâ Û1 ǼŸŎâ ÛVS (ȯ/ȯzŋ 1) ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ ȷâzÂ3 ǨƠ ǦzzȍzţÂ

ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ ȤǺǺɫ :**VS** (ȯ ȯzŋ **0.2**) **Hydrochloric acid** ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ
.Ōŋ1000 Ž HCl ȸŋ ȟ 7.293 Ƀz3 ʡøǪǵ ŏǺţǺǝ ÛTS (ȯ/ȟ250~)

ǦŌÂÀÛöâ ţǺGǩǺǝ ȯzŸĦŧŸö ĘĒęǼöâ ÂĒȭÀǪöâ ȸŋ ĘŌĦǪöâ ʔÀƶ *:Method of standardization ȄĒĒŌǪöâ ǦŌÂÀü*
.200 ǦĦǺÔöâ Û1 ǼŸŎâ ÛVS (ȯ/ȯzŋ 1) ȭÂøzŸȭøǼĒTâ Ȑþ ȷâzÂ3 ǨƠ ǦzzȍzţÂ

ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ ȤǺǺɫ :**VS** (ȯ ȯzŋ **0.02**) **Hydrochloride acid** ȭÂøzŸȭşøǼĒTâ Ȑþ ȯzŸȚ
.Ōŋ 1000 Ž HCl ȸŋ ȟ 0.7293 Ƀz3 ʡøǪǵ ŏǺţǺǝ ÛTS (ȯ/ȟ 250~)

ĞṎÂÛöä ţ̇ÂĠǨÂæ ȯζŸĦɫŸö ĘƐęÆöä ÂƐȭÀϘöä ȡŋ ĘȭĦϘöä ʔÀƶ *:Method of standardization ȄƐƐϘ̄öä ĞṎÂü*

.200 ĞĦȦÔöä Û1 ÆŸŎä VS (ȯ/ȯζŋ 1) Ȭ̈ÂøζŸȭşøÆƐŢä ȐƋ ȯζŸŢ ȷäζÂȝ ǨƠ Ĝζζȍζţä

Ȭ̈ÂøζŸȭşøÆƐŢä ȐƋ ȯζŸŢ ȤȦǺɫ :VS (ȯ ȯζŋ **0.001**) **Hydrochloric acid** Ȭ̈ÂøζŸȭşøÆƐŢä ȐƋ ȯζŸŢ

.Ōŋ 1000 Ž HCl ȡŋ ŊŸŋ 36.47 Ƀζȝ ʔøϘǵ ŏÂţÂæ ÛTS (ȯ/ȟ 250~)

ĞṎÂÛöä ţ̇ÂĠǨÂæ ȯζŸĦɫŸö ĘƐęÆöä ÂƐȭÀϘöä ȡŋ ĘȭĦϘöä ʔÀƶ *:Method of standardization ȄƐƐϘ̄öä ĞṎÂü*

.200 ĞĦȦÔöä Û1 ÆŸŎä ÛVS (ȯ/ȯζŋ 1) Ȭ̈ÂøζŸȭşøÆƐŢä ȐƋ ȷäζÂȝ ǨƠ Ĝζζȍζţä

.ĞƐöşǻ ĞƐəÂƐɫƐȭ ĞƐǓDZÀŋ ǵǻÂŋ :**Hydrochlorothiazide RS** ÆÀàÂƐϘşøζŸȭşøÆƐȽ

Ž ǵǻşÀζɉä Ž ȣζȍζŋ ζȽ Âɫȭ ȷşÂƐǨøζȭşøÆƐŢä ŌɫȞϘÊÀ .$C_{21}H_{30}O_5$:**Hydrocortisone R** ȷşÂƐǨøζȭşøÆƐȽ

.167 ĞĦȦÔöä Û2 ÆŸŎä

.ĞƐöşǻ ĞƐəÂƐɫƐȭ ĞƐǓDZÀŋ ǵǻÂŋ :**Hydrocortisone RS** ȷşÂƐǨøζȭşøÆƐȽ

.ĞƐöşǻ ĞƐəÂƐɫƐȭ ĞƐǓDZÀŋ ǵǻÂŋ :**Hydrocortisone acetate RS** ȷşÂƐǨøζȭşøÆƐŢä ğÂϘƐȅÛ

: **R** (ĞÂţÂæ **30**) ƙDZşøÆƐŢä ÆƐÊȭşƘæ **TS** (ȯ ȟ **330~**) **Hydrogen peroxide** ƙDZşøÆƐŢä ÆƐÊȭşƘæ

.(97 ĞĦȦÔöä Û1963 ÛSRIP)

ĞæζÊŢ Û$C_2H_5O_2$ ȡŋ %20 ȡȝ Ȭ̈ÕÀ ɼ Âŋ ʔŸȝ Ƀζϙȝ :**Hydroxyethylcellulose R** àζȯζŸȅ ŌƐǯÀÛ ɄÊȭşøÆƐȽ

.ĞÀȦŎä ǵǻÂţä ɃÛ ţζDZÀȯÂæ

.ĞĦəäÀöä Ĝƺƺȝ ÜǵÀȦÔöä ɃÛ ăøÂȓ şÛ ȐƐæÛ ȷζŸæ ÛĘəÂęø ȡŋ ĞȦȯǘŋ ÛǵÀȦÀƐƁŋ ĞŸϘȭ *:Description Ȥȍζöä*

ǴǴÔǨ ÛŏÂţä Ž ğÂȝÂȅ ǵƺȝ ǵƺŋ ȝȭ̈Âöä ÆȞæ ÜTS (ȯ/ȟ 750~) ȯζφÂǯÀϙä Ž ÆƐŸɫȝ Ğæäşæ Ƙȡ *:Solubility ĞƐφÂæşǾöä*

.ŏÂţä Ž ȷÂæşǾöä ǵÀǵ

ȡŋ Ōŋ 200 ȣÂȒÀ ÛĞƐDZÂDZà ǵǻäÆÊæ ǵǻşÂŋ ĞƐüşÀƯ ĞŸDZζǵ ɃÛ ȟ 2 Ȭ̈ÕÂɫ *:Colour of solution ȯζŸȽä ȷζȯ*

ăşǾǨ ʔøϘǵ ĞƐŸɫȞöä ȻǾȽ ǻÂȞǨ .ĞȭƐęǻ 30 ǵƺŋ øäÀȭ̈ϘȅŸö ȭ̈ÀϘÀş ÛȐǺɫ ÛR ȷζæÀȮöä ÆƐÊȭÛ ɄəÂÂϘ ȡŋ ɃÂʅä ŏÂţä

øÂϘϘȵɼ ĞǵÂȊÀöä ŞÂƠ) ȷζŸöä Ĝƺƺȝ ȷζȮϘζ ÜĞǵÂȊÀöä ȡŋ Ōŋ 5 ÆęäÀÀ .ÀȾDZĦŀ ǯÂDZà ȯŸȵ ȡŋ ĜȊÀǨş ǵǻÂţä

.(ĞÀζŸȭ̈öä şÛ Ğȓζɫƹä

øÀȮǨ .øäÀȭ̈ϘȅŸö ȭ̈ÀϘÀş ÛȭÀĦɫ ÛŏÂţä ȡŋ Ōŋ 25 øäÆȭ̈ŋ ȟ 1.0 ɃÛ ȣÂȒɫ *:Loss on drying ȤƐǺDZϘÀæ ÆȭÀȭ̈ä*

ɼ Ü°ȳ110 ǵøäÀǵ ĞDZøǻ Ž ǨæÂǯöä ȷàζöä ʔøϘǵ ȤȦDZɫş ɃəÂŋ ȳÂƋ ʔŸȝ ÀǺɫ .ȷÂæşǾöä ʔøϘǵ ĞƐŸɫȞöä ȻǾȽ

.(ĞÊÀÀȭ̈ţä ŌDZɉ ĞÀȦŎä ǵǻÂţä ŞÂƠ) .ȟ/ȟ 0.10 ȡŋ ÀǯȭÛ ÆȭÕÀÀ

ȷζȯ ŌDZɉ øÂϘϘȵɼä ȡŋ ȷϘÂǨ ɄøϘöä ĞǵÂȊÀöä ȡŋ Ōŋ 10 ɃÛ ȣÂȒÀ *:Acidity or alkalinity ĞÀζŸȭ̈öä şÛ Ğȓζɫƹä*

0.5 ... TS ...
(0.01) VS ...

Determination of ... *Assay*
0.20 ... 0.10 – 0.05 ... 0.5 ... (145 ... 1 ...) "methoxyl
(970~) TS ... 0.5 ...
10 ... 60 ... R ...
0.035 ...
."Determination of methoxyl ...
1.018 ... VS (0.1) ... 1 ...
.$C_2H_5O_2$

Hydroxyethylcellulose TS ...

2.0 ... 100 ... 50 ... *Proceduer*
20 ... 15 ... 15 ... 1 ... 15 ... R ...

Note ...

(1963 SRIP) NH_2OH,HCl **Hydroxylamine hydrochloride R** ...
.(99 ...

(-)-3-(4-Hydroxy-3-methoxyphenyl)-2- RS ... -2-(... -3- ... -4)-3-(-) ... **methylalanine RS**

Ibuprofen RS ...

.$C_3H_4N_2$ ... %99.0 ... .$C_3H_4N_2$ ... **Imidazole R** ...

Description ...

.TS (750~) ... *Solubility* ...

.°93 – 89 *Melting range* ...

0.5 ... *Sulfated ash* ...

VS (0.05) ... 50 ... 0.3 ... *Assay* ...
VS (0.05) ... 1 ... TS ...

.$C_3H_4N_2$ ȸǊ ŊŸŊ 6.808

Imidazole, recrystallized, R Ûgǿǭ̈ŸǇöä ắÅȞţä ÛȯşȁäǼȄȢǙ

ǒÅǞǓ ÛǰŸǫ ȳÅþ Ž ắƎĄş R ȸǹÅÊöä ȸĄǭŏǭǪöä ȸǊ ŌǊ 100 Ž R ȯşȁäǼȄȢqä ȸǊ ȟ 25 ǡäǾĄ :*Procedure ǒäǞǱqå*

ȴeȁöä ğäǽ şǓ 54 ȴeȁöä ğäǽ whatman JÅǪåş ǴȄǐȀǩ ȧǿş ȯÅȶȞǪèÅǽ ȚÒţÅǽ ǴȄǐȀǪöÅǽ ğäǿǭŸǇöä ŌÔÅł .ȰĄȀȞǪöä

ƘǫɉǡȸǊ ŌǊ 50 ǦäȁÅÕǽ ǦƟÅǼöä ğäǿǭŸǇöä ŌÊ8ǩ .JÅÒŋqä ǿǼę ȣÅAƨä ƾøǪǵ ȚÒţÅǽ ÛǴȄǐȀǪöäş gǿǭ̈ŸǇöä ắÅȞǩ .541

.JÅÒŋqä ǿǼę ȣÅAƨä ƾøǪǵ ȬǪş ƘǫɉÅǽ ǴȄǐȀǪöä ȧǿş ƾŸǯ ğäǿǭŸǇöä ŌÊ8ǩ Ż ǦȄŸȶȞöä ȻǾŁ ǿȁÔǩ .ǴǐȀĄş R

ǦäȁÅę şǓ ȯÅÔèÅǽǭŸȄȭ 0.6 ȸǯ ǼĄÂĄ Ɏ) ȐȦÅĄŋ Ȕ8ȓ ǨƠ ǦęȁǾöä gǿäÅǵ ǦDZǿắ Ž ȤÅƟş ǴÛÊŋ ĘǦȕ ƃǓ ŌȭĄ

.R ÛȤÅƒ ÛÅÒȄŸȄÊöä ǦŋŸŁ ȧǭǭ .(ĘǦȁ ȴŸŋ 5

.ȳÅÒǵüǽ ǦŌŸ8ŋ ǦĄşÅǵ Ž JÂƩ :*Storage ȸĄÂǺǪöä*

Imidazole/mercuric chloride TS ĘǦȁÂöä ǼĄǿǭŸȭ ȯşȁäǼȄȢǓ ȯǭŸȚ

Ȑþ ȸǊ ŌǊ 10 ȣÅȐĄş ǒÅţä ȸǊ ŌǊ 60 Ž R gǿǭŸǇöä ắÅȞţä ȯşȁäǼȄȢqä ȸǊ ȟ 8.25 ǡäǾĄ :*Procedure ǒäǞǱqå*

ĘǦȁÂöä ǼĄǿǭŸȭ ȯǭŸȚ ȸǊ ŌǊ 10 ÛgȁÛȰǭ gȁÛę ÛȀȶǪÊţä ȰĄȀȞǪöä ǨƠ ȣÅȐł .VS (ȯ/ȯǭŋ 5) ȰĄǿǭŸȭşǿǼȄȚä

ȯǼȞł .ȀǯȭǓ ǒȔǦǽ ĘǦȁÂöä ǼĄǿǭŸȭ ȯǭŸȚ ǦǭÅȓüǽ ȀǹǓ ȯǭŸȚ ȀȐƷş ƾŋȀł ÛȴǝÅȡ ȯǭŸȚ ŌÒÎǩ äǽǓ .TS (ȯ/ȟ 2.7)

ǿäǼŌŋ ȣÅȐĄş (Ōŋ 4 ǦäȁÅę ǼŸÛǪĄ) VS (ȯ/ȯǭŋ 5) ȰĄǿǭŸȭşǿǼȄȚä Ȑþ ȯǭŸȞŋ 0.05 ± 6.80 ƃǓ ȯÅŁÅǦöä

.Ōŋ 100 ȴDZǵ ƾŸǯ ȯǭÔȞŸȭ ǒÅţä ȸǊ ȣÅȭ

.ǦȄȭşắ ǦȄǝÅȄŧȄȭ ǦȄȞDZȀŋ gắÅŋ :**Indometacin RS** ƘèÅǪȄŋşǼǬǓ

:**Iodine /ethanol TS** ȯǭǬÅǯĄǓ ắǭȄöä ȯǭŸȚ

ƾŸǯ ȯǭÔȞŸȭ TS (ȯ/ȟ 750~) ȯǭǬÅǯĄqä ȸǊ ȣÅȭ ǿäǼŌŋ Ž R ắǭȄöä ȸǊ ȟ 10 ǡäǾł :*Procedure* : *ǒäǞǱqå*

.Ōŋ 1000 ȴDZǵ

.ǦȄȭşắ ǦȄǝÅȄŧȄȭ ǦȄȞDZȀŋ gắÅŋ :**Isoniazid RS** ǼĄȁÅȄǬşÂĄǓ

.G ǿǭ8ŸȄÊȄȭ :**Kieselguhr R1** (ȀŁǭƨä ȄȄȭ) ǿǭ8ŸȄÊȄȭ

40ş 10 ƘǽǡÅŧȄÊƨä ȴDZǵ Ȕèǭǫŋ ÛɃắÅŋȀöä ƃǓ ǡǿÅȓ – ȐȄǽǓ Jǭǽ ȧǭȞÊŋ :*Description Ǭȯǭöä*

.hemihydrat ğäǿǼȄȚä ǦȄÅÔǬ ÛȳǭȄÊöÅÒöä ğÅAŸè ȸǊ ȟ 150 ǦäȁÅę ŊŸȭ 1 Ōȭ Ž Ƀǭƺ ÛȀǪŋşȁÅÒŋ

.GF254 ǿǭ8ŸȄÊȄȭ :**Kieselguhr R2** ǿǭ8ŸȄÊȄȭ

ÛȀǪŋşȁÅÒŋ 40ş 10 ƘǽǡÅŧȄÊƨä ȴDZǵ Ȕèǭǫŋ ÛɃắÅŋȀöä ƃǓ ǡǿÅȓ – ȐȄǽǓ ȧǭȞÊŋ :*Description Ǭȯǭöä*

(ŊŸȭ/ȟ 15 ǦäȁÅę gắÅǯ) ǦȄǭÅȭ ǦȄŧȭş ğäǿǼȄȚä ǦȄÅÔǬ ÛȳǭȄÊöÅÒöä ğÅAŸè ȸǊ ȟ 150 ǦäȁÅę ŊŸȭ 1 Ōȭ Ž Ƀǭƺ

[illegible] 254 [illegible].

Kieselguhr R3 [illegible]:

Description [illegible]: [illegible] 170 [illegible] 200 [illegible].

Kieselguhr R4 [illegible]:

Description [illegible]: [illegible] 70 – 150 [illegible].

Kieselguhr R5 [illegible]:

Description [illegible]: [illegible] 10 [illegible] 40 [illegible].

Levarterenol hydrogen tartrate R [illegible]: $C_8H_{11}NO_3,C_4H_6O_6,H_2O$. [illegible] 99% [illegible] $C_8H_{11}NO_3,C_4H_6O_6$ [illegible].

Description [illegible].

Solubility [illegible] (~750 [illegible]) [illegible] TS [illegible] R.

Specific optical rotation [illegible] 50 [illegible] -10 to -13° $[\alpha]_D^{20°C}$.

Water [illegible]: Determination of water by "the Karl Fischer Methode" A ([illegible] 1 [illegible] 145) [illegible] 0.5 [illegible] 45 [illegible] 58 [illegible].

Assay [illegible]: [illegible] 0.4 [illegible] R [illegible] Non-aqueous titrateion" ([illegible] 1 [illegible] 142) A [illegible] 0.1 VS [illegible] 1 [illegible] 0.1 VS [illegible] 31.93 [illegible] $C_8H_{11}NO_3, C_4H_6O_6$.

Levodopa RS [illegible].

Lidocaine RS [illegible].

Lindane RS [illegible].

Lithium R [illegible]: Li.

¢ÕÀÀæ ÆÕÀÀ ÛɄȒζ – ɃåÀŋǿ ɹζŸæ ¢Àŋ ÆDZàÀü ţζÛÕŋ ǴÛѐ ɹζÒÀ ɃÀü (ÂĈǭ) ɹÆĤŋ :*Descripton* *Ȥòζǿǟ*

.ŏǟζŢǟ Ž Ğȝ̀ÀÊǽ

Ž āǟşǽ ÜÿζĚǮĚŸöǟ ÆĚÊõşǿÆĚĿ ȸŋ ÌŕζŸŢş ƙDZşǿÆĚŢǟ ÆĚÛĤŋ ÛöÀţǟ ȝŋ ǥÆÎǽ Õȝ̀ÀÀǪÀ :*Solubility* *ǴĚǭÀǽşǾǟ*

.R ƘǭɉǞ Ž ÆĚŸŧȝ āǟşǽ Ƙɖ ÜÿζĚǮĚŸöǟ ÆĚÊõζǮĚŋ ȸŋ ÌŕζŸŢş ƙDZşǿÆĚŢǟ ÆĚÛĤŋ ÛR ȯζǫÀǮĚţǟ

:VS (ȯ ȯζŋ **0.1**) **Lithium methoxide** ÿζĚǮĚŸöǟ ÆĚÊõζǮĚŋ ȯζŸŢ

ȸŋ ȣÀõ ǿǟÆÕŋ ȣÀȒÀş R ȯζǫÀǮĚţǟ ȸŋ Õŋ 150 Ž R ÿζĚǮĚŸöǟ ȸŋ ȟ 0.694 āǟǾÀ :*Procedure* *ǒǟÄDZɋǟ*

.Õŋ 1000 ɭDZǵ ɁŸȝ ȯζÔĤŸö R ȸÀζǿζǪöǟ

Ęζş ȯ/ȯζŋ 0.1 ÂĚõÀǪǽ ȯζŸɨ ĘĚęÆöǟ ÂĚõÀǪöǟ ȸŋ ĘÕĤǪöǟ ɁÀƶ :*Method of standardization* *ȄĚĚǪöǟ ǴÕÀÀü*

ÕĚǮĚŋ ɄǝÀÀǭ ȸŋ Õŋ 25 Ž R ÕÀşÂǿÆǤöǟ Ȑþ ȸŋ ÛČĚüζǤȒŋ Ǵǭşàζŋ Ûȟ 0.15 ǴǟǟÀę āǟǾÀ :ǴĚöÀǪöǟ ǴÕÀÀÛöǟ

ǥÀþ ȯζŸŢ ȯÀŧĤǪѐÀǽ ÛÀþɉǟ ɹζŸöǟ ğǟǽ ǴÀÀŢÀöǟ ǴÛÕǭ ɁǿǪǵ ÿζĚǮĚŸöǟ ÆĚÊõζǮĚŋ ȯζŸĤŋ ÀÀĤÀş R ÆĚŋÀŋǿζζ

Non-aqueous ɄǝÀŋŸöǟ Ùѐζöǟ Ž ǥÀÀĤţǟ" ɹǟζÀȝ ǨƠ ȣζòζŋ ζĿ Àŧõ ÛÀĤÎŧõ TS ȯζǫÀǮĚŋ/ȸÀÆöÀÀĚÒöǟ

ȯζŸŢ ȸŋ Õŋ 1 üζÀÒÀ ÕÀşÂǿÆǤöǟ Ȑþ ȸŋ ŊŸŋ 12.21 Õõ .(142 ǴĤÀÔöǟ Û1 ÆŸÕǟ) B ǴÕÀÀÛöǟ Û"titration

.ÀǿζζȯÀŧĤǪѐŕǟ ÕǤę ÿζĚǮĚŸöǟ ÆĚÊõζǮĚŋ ÕĚöÀŢ ȄĚÕĬ ɹÛ Æƶ .VS (ȯ/ȯζŋ 0.1) ÿζĚǮĚŸöǟ ÆĚÊõζǮĚŋ

.(108 ǴĤÀÔöǟ Û1963 ÛSRIP) :**Litmus R** ȄŧÎöǟ åÀǤȝ

:**Litmus TS** ȄŧÎöǟ åÀǤȝ ȯζŸŢ

Ğȝ̀Àѐ 1 ǥÆŋ TS (ȯ/ȟ 710~) ȯζǫÀǮÀɋǟ ȸŋ Õŋ 40 ȝŋ R ȄŧÎöǟ åÀǤȝ ȸŋ ȟ 10 ɁŸȣÀ :*Procedure* *ǒǟÄDZɋǟ*

åÀǤȝ ɭȒŢŀ .TS (ȯ/ȟ 710~) ȯζǫÀǮÀɋǟ ȸŋ Õŋ 30 ǿǽ ƙǨÀŋ ǴĚŸŧĤöǟ ȻǾĿ ǿÀÒǨ ÛŽÀÔöǟ ÕǝÀÊöǟ ÆĚÆĚĤǽ ƶÀÛÀş

.ǴìÀÀş ǒÀţǟ ȸŋ Õŋ 100 ǿǽ ȯζÊȣţǟ ȄŧÎöǟ

.(109 ǴĤÀÔöǟ Û1963 ÛSRIP) :**Litmus paper R** ȄŧÎöǟ åÀǤȝ ȧǿş

āǟÀÎǭѐŕǟ Ž ȯÀŧĤǪѐŸö ǴǤѐÀŋ ǴDZǿå ζĿ .20000 ȯζÒĚŸɖ ƙŸĚǮÀÛ ÆÀÆȝ :**R** (ǴÀÀÂDZ **20**) **Macrogol** ȯζɖşÀõÀŋ

.ɃàÀȣöǟ ÕǝÀÊöǟ

ǴǟǟÀę Ƀζȝ R ÿζÀÂǿÀȣţǟ ğÀÀŸѐ ȯζŸŢ :**TS** (ȯ ȟ **50**) **Magnesium sulfate** ÿζÀÂǿÀȣţǟ ğÀÀŸѐ ȯζŸŢ

.ÀǪö 1 Õõ Ž $MgSO_4$ ȸŋ ȟ 50

.(113 ǴĤÀÔöǟ Û1963 ÛSRIP) $HgCl_2$:**Mercuric chloride R** ĘǤǝÂöǟ ÆÀǿζŸõ

ȸŋ ȟ 6.5 ǴǟǟÀę Ƀζȝ R ĘǤǝÂöǟ ÆÀǿζŸõ ȯζŸŢ :**TS** (ȯ ȟ **65**) **Mercuric chloride TS** ĘǤǝÂöǟ ÆÀǿζŸõ ȯζŸŢ

.(ǺǤÀÕǩ ȯ/ȯɀȠ 0.25) ÀǪǶ 1 ŌÕ Ž $HgCl_2$

ȡȠ ȟ 2.7 ǦǟÀȩ ɃɀƷ R ȨǤǝÂǖǟ ǼǺǿɀŸÕ ȯɀŸŢ :TS (ȯ ȟ 2.7) **Mercuric chloride** ȨǤǝÂǖǟ ǼǺǿɀŸÕ ȯɀŸŢ

.ÀǪǶ 1 ŌÕ Ž $HgCl_2$

.(115 ǦȞǺÔǖǟ Û1963 ÛSRIP) Hg :**Mercury R** ȨǤǝÂǖǟ

.ǦǰǖȘǻ ǦǰǝǺǰȶǰÕ ǦǰȟDZÀȠ ǥǻÀȠ :**Methyldopa RS** ǺǣȘǻ ŌǰǮǰȠ

.(119 ǦȞǺÔǖǟ û1963 ûSRIP) Û$C_6H_{12}O$ ÛɈɀǪǰèǕ ŌǰǣȘÀǣȘÂǺǕ :**Methylisobutylketone R** ɈɀǪǰÕ ŌǰǨɀǣȘÂǺǕ ŌǰǮǰȠ

.$C_8H_{10}N_2O_3S$:***N*-Methyl-*N*-nitrosotoluene-4-sulfonamide R** ǼǰȠǺǪɀǺŸè -4- ȡǺɀǿɀǨȘàȘÀǪ -*N*- ŌǰǮǰȠ - *N*

.ÀǺòǕ ÛɃǿɀŸǣ ȧɀȞÊȠ :*Description* *Ȥòɀǖǟ*

.R ǨǪɉȘ TS (ȯ/ȟ 750~) ȯɀǪǺǮǺɋǟ Ž ǟǟȘǣ ÜòǺȶǟ Ž ǟǟȘǣ Ǩȡ :*Solubility* *ǦǪǺǣȘǾǖǟ*

.°ÿ60 ǦǟÀȩ :*Melting temperature* *ǿǺȚÔǪȓǟ ǥǿǟÀǵ ǦDZǿǻ*

.R ɈɀǪèɉǟ Ž R ŌǰǮǰȶǟ ǦǰǖǺÕǨÀǣ ȡȠ ƷǤÎȠ ȯɀŸŢ :**Methyl orange/ acetone TS** ɈɀǪèǕ ŌǰǮǰȶǟ ǦǰǖǺÕǨÀǣ ȯɀŸŢ

.$C_5H_{12}N_2$:***N*-methylpiperazine R** ȡǺǟǟǨǤǰǣ ŌǰǮǰȠ *N*

.ȯ/ȠŸÕ 0.902 p_{20} :*Mass density* *ǦŸǪȮǖǟ ǦɀǺǮÕ*

1.466 n_D^{20} :*Refractive index* *ɃǿǺÊȮǪɋǟ ǼÊǺȶǟ*

.ɃǟǺ8ǖǟ ŌǝǺÊǖǟ ǟǟÀÎǪèȓǟ Ž ȯǺȶȞǪèŸǶ ǦǤèǺÀȠ ǦDZǿǻ :**Methyl silicon gum R** ŌǰǮǰȶǟ ɈɀȮǰŸè ȠȶÒ

.ǦǰǖȘǻ ǦǰǝǺǰȶǰÕ ǦǰȟDZÀȠ ǥǻÀȠ :**Methyltestosterone RS** ɈȘǨǪèɀǪÊǨ ŌǰǮǰȠ

ŌǰǮǰȠ ǼǺǿɀŸÕ ȡȠ ȯɀŸŢ ɃɀƷ :**TS (ȯ ȟ 1) Methylthioninium chloride** ÿɀǰǼǪɀǰǪ ŌǰǮǰȠ ǼǺǿɀŸÕ ȯɀŸŢ

.ÀǪǶ 1 ŌÕ Ž $C_{16}H_{18}ClN_3S$ ȡȠ ȟ 1 ǦǟÀȩ R ÿɀǰǼǪɀǰǪ

[3H-2,1-benzoxathiol-3- Tetrasodium ÿɀǺǻɀÔǖǟ ȽƷǺǣǿ :**Methylthymol blue R** ȯɀȶǰǮǖǟ ŌǰǮǰȠ Ǧȩǿà ylidenebis [(6-hydroxy-5-isopropyl-2-methyl-*m*-phenylene)methylenenitrilo]] tetraacetic acid S,S-

.dioxide; $C_{37}H_{44}N_2Na_4O_{13}S$

.ȽǿǺǤǖǟ ɃǕ ǟǿǺȓ – ǻɀèǕ ȧɀȞÊȠ :*Description* *Ȥòɀǖǟ*

.TS (ȯ/ȟ 750~) ȯɀǪǺǮǺɋǟ Ž ǺǼDZ ɈǺǣȘǾǖǟ ǴǰȞȉ ÜòǺȶǟ Ž ɈǺǣȘǾǖǟ Àǵ :*Solubility* *ǦǪǺǣȘǾǖǟ*

:**Methylthymol blue mixture R** ȯɀȶǰǮǖǟ ŌǰǮǰȠ Ǧȩǿà ǰǺȠ

.R ÿɀǰèǺǨɀǤǖǟ ǦǟÀǪ ȡȠ ǒÂDZ 100 ƷȠ R ȯɀȶǰǮǖǟ ŌǰǮǰȠ Ǧȩǿà ȡȠ ǼǦǟȘ ǒÂDZ ǮÂȶȴ :*Procedure* *ǒǟÀDZɋǟ*

.ǦǰǖȘǻ ǦǰǝǺǰȶǰÕ ǦǰȟDZÀȠ ǥǻÀȠ :**Metronidazole RS** ȯȘàǟǼǰȘÀǪǰȠ

. $C_{10}H_8O$ ⁏**1-Naphthol R** ȯζ̌ζȦ̍φ **- 1**

.ƨȂŀư ÛǦĦɘȁȀȫȁ ÜȒŀȁ̈ Ƀǿζ̈Ÿȁ ȧζĦÊɳ ʂ̈Û Ûȷζ̈Ÿȫȁ ǦƩǼȝ ğȁǿζ̈Ÿȁ *:Description ζ̧ȍζȫ̈ȁ*

ǅǼȝ ÛȲŸȩ ȴŀȶɖ ȯζ̈ŸƮ ȬȮÎ Ǽȩ) TS (ȯ/ȟ 750~) ȯζφȦ̌ɋȁ ȸɳ ȫȁȂDZÜ 5 Ž ȁ̄ȁʂǽ *:Solubility ǦȂȁȦ̌ʂǾȫȁ*

.(ȀȂȬǩ ȷζ̈Ÿȫȁ ǅǼȝ ʂ̈Û ȷζ̈Ÿȫȁ

.°ȳ96 – 93 *:Melting Range ǿȦ̌ȚÔφɼȁ ȯȦ̌ƒ*

.ȟ/ɳŸɳ 0.5 ȸȝ ǼȂȀȂ ɼ *:Sulfate ash ǨȂ̌ŸÊţȁ ǻȦ̌ɳȀȫȁ*

⁏**1-Naphthol TS1** ȯζ̌ζȦ̍φ **- 1** ȯζ̈ŸƮ

(ȯ/ȟ 150~) ȳζȂǻζÔȫȁ ǼŀÊȭʂǿǼŀȽ ȯζ̈ŸƮ ȸɳ Ȭ̄ɳ 3 Ž R ȯζ̌ζȦ̍φ –1 ȸɳ ȟ 0.10 ȁ̄ȁǾȂ *:Procedure ȫ̈ȁȀDZɋȁ*

.Ȭ̄ɳ 100 ȴDzǵ ɁŸȝ ȯζÔĦŸȫ ȫȦ̌ţȁ ȸɳ ȣȦ̌ȭ ǿȁǼȬ̄ɳ ζȦ̌Ƹʂ TS

.ȁǿζζ ȯȦ̌ȶĦȩèɼȁ ȬǦȩ TS1 ȯζ̌ζȦ̍φ –1 ȯζ̈ŸƮ ȀȒĦƚ ȷ̈Û Ǣʐ *:Note ǦȚǵŸɳ*

.$C_{27}H_{20}O_3$ ⁏**1-Naphtolbenzein R** ƙȂÂǿȂ̈ȁ ȯζ̌ζȦ̍φ **1**

.ƨȂ̈ȶΣȁ ƂÛ ȁ̄ǿȦ̌ȑ – ɄǿȂ̈ȁ ȧζĦÊɳ *:Description ζ̧ȍζȫ̈ȁ*

R ƙȫɉʂ R ȸȂÂǿȂǦȫȁʂ TS (ȯ/ȟ 750~) ȯζφȦ̌ɋȁ Ž ȁ̄ȁʂǽ ÜȫȦ̌ţȁ Ž ȀŸȶȝ ȁ̄ȁʂǽ ƙɖ *:Solubility ǦȂȁȦ̌ʂǾȫȁ*

.R ɄDzŸ̌ȫȁ Ȭ̃ŀȩèɉȁ Ȓ̀ƥʂ

⁏**1-Naphtholbenzein/acetic acid TS** Ȭ̃ŀȩèɉȁ Ȓ̀ƥ ƙȂÂǿȂ̈ȁ ȯζ̌ζȦ̍φ **1** ȯζ̈ŸƮ

R ɄDzŸ̌ȫȁ Ȭ̃ŀȩèɉȁ Ȓ̀ƥ ȸɳ ȣȦ̌ȭ ǿȁǼȬ̄ɳ Ž R ƙȂÂǿȂ̈ȁ ȯζ̌ζȦ̍φ –1 ȸɳ ȟ 0.2 ȁ̄ȁǾȂ *:Procedure ȫ̈ȁȀDZɋȁ*

.Ȭ̄ɳ 100 ȴDzǵ ɁŸȝ ȯζÔĦŸȫ

⁏***N*-(1-Naphthyl)ethylenediamine hydrochloride R** ƙɳ̈Û ɄɘȦ̌Ȃǭ ƙŸŀ̌ȂÛ (Ȭ̄ŀ̌ζȦ̍φ **- 1**) **-** ***N*** ǼȂǿζ̈ŸȭʂǿǼŀȽ

.(124 ǦĦȦÔȫȁ Û1963 ÛSRIP) $C_{12}H_{14}N_2,2HCl$

N*-(1-Naphthyl)ethylenediamine hydrochloride** ƙɳ̈Û ɄɘȦ̌Ȃǭ ƙŸŀ̌ȂÛ (Ȭ̄ŀ̌ζȦ̍φ **- 1**) **-** ***N ǼȂǿζ̈ŸȭʂǿǼŀȽ ȯζ̈ŸƮ

ȸɳ ȟ 5 ǦȁȁȀȩ R ƙɳ̈Û ɄɘȦ̌Ȃǭ ƙŸŀ̌ȂÛ (Ȭ̄ŀ̌ζȦ̍φ-1)-N ǼȂǿζ̈ŸȭʂǿǼŀȽ ȸɳ ȯζ̈ŸƮ Ƀζȝ ⁏**TS** (ȯ ȟ **5**)

.ȀȬ̀ 1 Ȭ̄ȭ Ž $C_{12}H_{14}N_2,2HCl$

N*-(1-Naphthyl)ethylenediamine hydrochloride** ƙɳ̈Û ɄɘȦ̌Ȃǭ ƙŸŀ̌ȂÛ (Ȭ̄ŀ̌ζȦ̍φ **- 1**) **-** ***N ǼȂǿζ̈ŸȭʂǿǼŀȽ ȯζ̈ŸƮ

ȟ 5 ǦȁȁȀȩ R ƙɳ̈Û ɄɘȦ̌Ȃǭ ƙŸŀ̌ȂÛ (Ȭ̄ŀ̌ζȦ̍φ -1)-N ǼȂǿζ̈ŸȭʂǿǼŀȽ ȸɳ ȯζ̈ŸƮ Ƀζȝ ⁏**TS** (ȯ ȟ **1**)

.ȀȬ̀ 1 Ȭ̄ȭ Ž $C_{12}H_{14}N_2,2HCl$ȸɳ

N*-(1-Naphthyl) ethylenediamine** [illegible] -1)-N*** [illegible] **:hydrochloride/ethanol TS**

[illegible] (-1 [illegible]) *–N* [illegible] 5 [illegible] *:Procedure* [illegible] (~750 [illegible]) TS [illegible] 1000 [illegible].

[illegible] **Nicotinamid RS** [illegible].

[illegible] **Nicotinic acid RS** [illegible].

[illegible] **Nictric acid, fuming, R** [illegible] HNO_3 (SRIP 1963 [illegible] 126) [illegible] *d*~1.5.

4 - Nitroaniline R [illegible] - 4 **R** [illegible] : $C_6H_6N_2O_2$ (SRIP 1963 [illegible] 127).

[illegible] –4 **4-Nitroaniline TS1:**

[illegible] –4 [illegible] 5 [illegible] *:Procedure* [illegible] (1 [illegible]) VS [illegible] 1000 [illegible].

[illegible] - 4 **4-Nitroaniline TS2:**

[illegible] –4 [illegible] 0.4 [illegible] *:Procedure* [illegible] 60 [illegible] (1 [illegible]) VS [illegible] 15 [illegible] (100 [illegible]) TS [illegible] R [illegible].

:Note [illegible] –4 [illegible] TS2 [illegible].

4-Nitrobenzoyl chloride R [illegible] -4 [illegible] ***p*-nitropenzoyl chloride R** [illegible] : $C_7H_4ClNO_3$ (SRIP 1963 [illegible] 128).

Nitrogen, oxygen-free, R [illegible] R [illegible] TS [illegible].

1-Nitroso-2-naphthol-3,6-disodium [illegible] –1 [illegible] -2- [illegible] 3- [illegible] -6 [illegible] **disulfonate R:** -1 [illegible] -2- [illegible] -3 [illegible] -6 [illegible] R : $C_{10}H_5NNa_2O_8S_2$ (SRIP 1963 [illegible] 129).

1-Nitroso-2-naphthol-3, 6-disodium [illegible] - 2 [illegible] -2- [illegible] 3- [illegible] -6 [illegible] **disulfonat** **(2** [illegible]**) TS:** [illegible] -1 [illegible] –2- [illegible] 3- [illegible] -6 [illegible] R

.ÄǪǒ 1 Ǒõ Ž $C_{10}H_5NNa_2O_8S_2$ ȸŋ ȟ 2 Ǧǟǟ̈Äę

.ǦĚǒşǻ ǦĚəÅĚȶĚõ ǦĚȞDZÄ̀ŋ ǥǻÅŋ :**Norethisterone RS** ȷşǨǪÊĚǯŇǿζφ

.ǦĚǒşǻ ǦĚəÅĚȶĚõ ǦĚȞDZÄ̀ŋ ǥǻÅŋ :Norethisterone acetate RS ȷşǨǪÊĚǯŇǿζÅǒǟ ǧÅǪĚèǕ

:**Opalescence standard TS1** ȳζȶȣǒǟ ɃǿÅĚȞŋ ȯζŸȚ

Procedure ǒǟÄDZqǟ: ȤÅÅł 15 Ǒŋ ȸŋ ȯζŸȚ ɃǿÅĚȞŋ ȳζȶȣǒǟ ȸÅÂȴǟ TS ǿǟǼǑŋ ȣÅõ ȸŋ ǒÅţǟ ȯζÔȞŸǒ ɁŸȝ

.Ǒŋ 1000 ȴDZǵ

Shelf-life ǭȸÅÂǺǪǒǟ Äȶȝ: Ǒȶ̀ȞǪÊÅ ȯŸǹ 24 Ǧȝ̇Åè ǼȞǟ ȻǨȒƠ.

:**Opalescence standard TS2** ȳζȶȣǒǟ ɃǿÅĚȞŋ ȯζŸȚ

Procedure ǒǟÄDZqǟ: ȤÅƩ 5.0 Ǒŋ ȸŋ ȯζŸȚ ɃǿÅĚȞŋ ȳζȶȣǒǟ TS1 ǿǟǼǑŋ ȣÅõ ȸŋ ǒÅţǟ ȯζÔȞŸǒ ɁŸȝ ȴDZǵ

.Ǒŋ 100 .ȝÂȶł ǠĚDZ ȒÅȶş Ǒǒę ȯÅȶȞǪèɍǟ.

Note ǴȚǵŸŋ: ǠDZǟÅù TS2 ȳζȶȣǒǟ ɃǿÅĚȞŋ ȯζŸȚ ÄȒȜ ȷǕ Ǣƶ.

:**Opalescence stock standard TS** ȸÅÂȴǟ ȳζȶȣǒǟ ɃǿÅĚȞŋ ȯζŸȚ

Procedure ǒǟÄDZqǟ: ǡǟǿÅ 1.0 ȟ ȸŋ ǧÅÅŸè ȸÅǟǟǿǼĚȚǟ R Ž ǿǟǼǑŋ ȣÅõ ȸŋ ǒÅţǟ ȯζÔȞŸǒ ɁŸȝ ȴDZǵ 100

Ǒŋ ǒÄǪşõ ǿǟÄǑǪèɎǒ ǥǼŋ 6 - 4 ǧȝ̇Åè . ȣÅȒÅ ǕƂ 25.0 Ǒŋ ȸŋ ǟǿȽ ȯζŸɨǟ ȯζŸȚ ȸŋ 2.5 ȟ ȸŋ ǟţǯĚÅÅǨŋ R

.Ǧȝ̇Åè 24 ǥǼŋ ǿǟÄǑǪèɎǒ ǒÄǪşõ ǠǿǼĚDZ ȝÂƩ ǓǒÅţǟ ȸŋ Ǒŋ 25.0 Ž ǦǤǟǿǒǟ

Storage ȸÅÂǺǪǒǟ: ȷÂƩ Ž ǵÅşǦÅ ǟDZÅǠDZǦĚ ǹÅǒǦĚ ȸŋ ȞǒÅǟ ǡζĚÔÊǦĚȞǒǟ.

Shelf-life ȸÅÂǺǪǒǟ Äȶȝ: Ǒȶ̀ȞǪÊÅ ȯŸǹ ȸÅÄȚì ǼȞǟ ǪǒǞȒǨ.

:**Osmium tetroxide R** ȳζĚȢşɟǟ ǼĚÊõǕ ȜȝǟǿÅ .OsO_4

Caution ÄÅǾƠ: ǼǹÅǿȸǟ ǦǟÅȭǕ ǓȞŸǦǨǓ şǟɟȡÎǦĚ ǓţÅǺǕǦĚǓ şǟȥŸǼ.

Description ǒǟζǑǒȤ: ǓǦǦùÄǪÊŋ ǥǻÅŋ ȜŁş ǓǑǟÅÅǑ ǦÅǿζŸǟ ǦŸǪõ şǕ ǓÄÅǑǕ ȷζǒ ǧǟǣ ǓÄǣǕ ǑǑÎǟ ǧǟǿζŸǟ

.ǦȝǣɍǓ ǦĚȞəǟÄǒǟ ǓǑζȒŸǒ ǦèÅÊǵ.

Solubility ǒǟǿǟşǟǿǒǟ: ǦǟǟşǼ Ž ǒÅţǟ ȯζǠǯǵqǟş (ȯ/ȟ 750~) TS şǟɟǪǨ R.

:**Oxytetracycline hydrochloride RS** ǨŸǑĚèǟÄǪǪǒǟ ȜÊõşǕ ǼÅǿζŸõşǿĚŁ .ǦĚǒşǻ ǦĚəÅĚȶĚõ ǦĚȞDZÄ̀ŋ ǥǻÅŋ

:**Papaverine hydrochloride RS** ȸÅǨζÅǟǦǒǟ ǼÅǿζŸõşǿĚŁ .ǦĚǒşǻ ǦĚəÅĚȶĚõ ǦĚȞDZÄ̀ŋ ǥǻÅŋ

:**VS (ȯ ȯζŋ 0.05) Perchloric acid** ǑǿζŸõǨǦǒǟ Ȓƥ ȯζŸȚ

Procedure ǒǟÄDZqǟ: ȣÅȒÅ ǕƂ 900 Ǒŋ ȸŋ Ȓƥ ǑǪĚèɟǟ ȜDZǯǒǟ R1 Ž ǦDZǿǻ ǥǿǟÄǵ Ǧǟǟ̈Äę 25ȳ°Ǔ ǿǟǼǑŋ

[illegible] 15 [illegible] (1170~ [illegible]) [illegible] 4.2 [illegible] 1000 [illegible] R1 [illegible] 24 [illegible].

[illegible] *Water and method of standardization* [illegible] (0.1 [illegible]) [illegible] 213.

Petroleum, light, R1 [illegible]:

Description [illegible]: [illegible].

Boiling range [illegible]: 40 – 60°[illegible].

Mass density [illegible] p_{20}: 0.630 – 0.650 [illegible].

[illegible] **2-Phenoxyethanol R** [illegible]: $C_8H_{10}O_2$.

Description [illegible]: [illegible].

Miscibility [illegible]: [illegible] (750~ [illegible]) TS [illegible] R.

Mass density [illegible] p_{20}: 1.1 [illegible].

Refractive index [illegible] n_D^{20}: 1.537 [illegible].

Freezing point [illegible]: 12.0°[illegible].

[illegible] **Phenoxymethylpenicillin RS** [illegible].

[illegible] **Phenoxymethylpenicillin calcium RS** [illegible].

[illegible] **Phenoxymethylpenicillin potassium RS** [illegible].

[illegible] **2-Phenylethanol R** [illegible]: $C_8H_{10}O$. [illegible].

[illegible] **2-Phenylethanol TS** [illegible]:

Procedure [illegible]: 1 [illegible] 2 - [illegible] R [illegible] R [illegible] 50 [illegible].

[illegible] **Phenylhydrazine R** [illegible]: $C_6H_8N_2$ (SRIP 1963 [illegible] 140).

[illegible] **Phenylhydrazine hydrochloride R** [illegible]: $C_6H_8N_2,HCl$ (SRIP 1963 [illegible] 140).

:**Phenylhydrazine /sulfuric acid TS** ÕÀǿ ʐÀÝÊöä Ȑþ ȸÀäǿÆÊŁ ÕÆÆʐ ȯʐÝȚ

ȯʐÀʒÀɋä ȸɳ ÀÖĜÊɳ ȼǩǿʐÝæ ǥÀȞʈä ÛR ȸÀäǿÆÊŁ ÕÆÆʐ ÆÀǿʐÝÕşǿÆÊŁ ȸɳ ɳÝɳ 65 ǟäǾÀ *:Procedure ǿäÄDZɋä*

ȸɳ Õɳ 80ş TS (ȯ/ȟ 1760~) ÕÀǿʐÀÝÊöä Ȑþ ȸɳ Õɳ 170 ȸɳ ǰÀÂɳ ȸɳ ĜÊʐÀÕ ĜÊȶÕ Ž ÛTS (ȯ/ȟ 710~)

.Õɳ 100 ȴDzǵ ʔÝʒ ȯʐÔĦÝö ǒÀʈä

.ÀDZäÀü ÕÀǿʐÀÝÊöä Ȑþ/ȸÀäǿÆÊŁ ÕÆÆʐ ȯʐÝȚ ÀȒʒ ȷÛ Ǣʑ *:Note ǦȚǵɎɳ*

.ĜÊöşǻ ĜÊəÀÊȶÊÕ ĜÊȞDZÀɳ ǥÀɳ :**Phenytoin RS** ȸÀʐǬÆÆʐ

:**TS, 4.5** ǒÀŁÀæ **Phosphate/ citrate buffer** ğäÀǬÊè ğÀÀÊǮ Ǥəǿäǻ ȯʐÝȚ

ǒÀŁÀĜöä ȯÆȞķş ǒÀʈä ȸɳ Õɳ 30 Ž R ȳʐÀǻʐÔöä ĜÊəÀÀǭ ƙDZşǿÆÊȚä ğÀÀÊǮ ȸɳ ȟ 2.15 ǟäǾÀ *:Procedure ǿäÄDZɋä*

.TS (ȯ/ȟ 20) ÕÀÀǬÊÊöä Ȑþ ȯʐÝĦɳ 4.5 БÛ ȯʐÝĦȶÝö

.(141 ĜĦÀÔöä Û1963 ÛSRIP) $H_3PO_4,12MoO_3,24H_2O$:Phosphomolybdic acid R ÕÀÆĜÊöʐɳʐÀÊǮ Ȑþ

:**Phosphorus, red R** Àþɉä ÛǿʐÀÊÀÀöä

.ȸÕäǻ ÀþÛ ȧʐĦÊɳ *:Description ǵöʐä*

.ĜÀÀǺʈä ôʐȶΣäş ǒÀʈä Ž ǟäşæ Ƙȡ *:Solubility ĜǬÀÊşǾöä*

ȾəÀɳ ȳÀþ ʔÝʒ TS (ȯ/ȟ 300~) ÕǬǬèɉä Ȑþ ȸɳ Õɳ 30 ʒɳ ȟ 2.0 ȸǺÊŁ *:Soluble matter ĜäşǾöä ǥǻʈä*

ĜDZǿǻ Ž ȤÀʑş ȾəÀɳ ȳÀþ ʔÝʒ ĜǵÀìÀöä ȸɳ Õɳ 25 ÀǺĜŁ ÛĜìÀŁ ÛÕɳ 50 БÛ ȤÀǺŁ ÛǻƎŁ ÛĜÕÊęǻ 15 ǥÆɳ

.ɳÝɳ 50 ȸɳ ÀǯÕÛ ĜöÀȶǯöä ȷÀǩ ɍ ÜĜʒÀè 2 ǥÆɳ °ȳ110 ǥǿäÀǵ

ǥǻşÂɳ ĜǬäʐÛèä Ž R ȷʐæÀÒöä ÆÊÀÝè ȾəÀÀǭ ȸɳ Õɳ 20 ʒɳ ȟ 5.0 ȐǺŁ *:Yellow phosphorus ÀÀöɉä ǿʐÀÊÀöä*

ÀȚÊȶȡ ʔÀDZ Æę Ûȴè 0.5 ȴè 10 ÛĜÊìÀǩ Ĝęǿş ȸɳ ÙÀÀì ĜǵÀìÀöä Ž ÈȶȣÀş ÛĜìÀÀ ÛĜÊDZÀDZä ǥǻäÆÊæ

.ĜǨÕæ ĜÀÛ ÕÒÎǬǩ ɍ ÜöäʐȚä Ž ȣÀÀDzÝö ÕÀǬǩ ÛTS (ȯ/ȟ 80) ÂÊÕÀǬæ (II) ȃÀĦÀöä ğÀÀÝè ȯʐÝȚ Ž ÀÖĜÊɳ

(ȯ/ȟ 1760~) ÕÀǿʐÀÝÊöä Ȑþ ȯʐÝȚ ȧʐʐ ĶæÀǯöä ȷàʐöä ʔǿǬǵ ȤÀʑ *:Loss on drying ȤÊÀDZǬÀæ ÆÕÀöä*

.ȟ/ɳÝɳ 10 ȸɳ ÀǯÕÛ ÆÕÀÀ ɍ ÛTS

.(144 ĜĦÀÔöä Û1963 ÛSRIP) $H_2PtCl_6,6H_2O$:**Platinic chloride R** ƙǨŸĜöä ÆÀǿʐÝÕ

ȸɳ ȟ 63 ĜäÀę Ƀʐʒ R ƙǨŸĜöä ÆÀǿʐÝÕ ȯʐÝȚ :**TS** (ȯ ȟ **60**) **Platinic chloride** ƙǨŸĜöä ÆÀǿʐÝÕ ȯʐÝȚ

.ÀǬö 1 ÕÕ Ž H_2PtCl_6

:**TS Potassio-cupric tartrate** ȳʐÊèÀǩʐĜöäş ȃÀĦÀöä ğäÀüÀü ȯʐÝȚ

100 ȴDzǵ ʔÝʒ ȯʐÔĦÝö ǒÀʈä ȸɳ ȣÀÕ ǿäÆÕɳ Ž R (II) ȃÀĦÀöä ğÀÀÝè ȸɳ ȟ 7 ǟäǾÀ *:Procedure ǿäÄDZɋä*

Ōŋ 100 Ž R ÿz̧ăźzÔöä ÆÊõşøÆĿ ŵŋ ȟ 10ş ÿzÈèÅkzĜöäş ÿz̧ăźzÔöä ğäÀùÀù ŵŋ ȟ 35 ŸÔÀŋ āäØ .Ōŋ
.ÅĦŋ ƙözŸŧä Ÿõ ŵŋ ĞÅşÅÊŋ ÿzDzģ ǯÂq ÛĶÔę Ǩęzä òÅŧĦèŗä Ōęę .öÅţä ŵŋ

¦**Potassio-mercuric iodide TS** ÿzÈèÅkzĜöäş ĘĜəÂöä Æăźz òzŸŢ

Æăźz ŵŋ ȟ 5 ŸÔÀŋ āäØ ÜöÅţä ŵŋ Ōŋ 60 Ž R ĘĜəÂöä ÆøzŸõ ŵŋ ȟ 1.355 āäØ *:Procedure öäÄDZq*
.öÅţÅä Ōŋ 100 БÜ ZÅƩş ɉŗzŸŧä ǯÂŧł ÜöÅţä ŵŋ Ōŋ 20 Ž R ÿzÈèÅkzĜöä

¦**Pottassio-mercuric iodide, alkaline, TS** ÛBzŸŌöä ÛÿzÈèÅkzĜöäş ĘĜəÂöä Æăźz òzŸŢ

ÛöÅţä ŵŋ Ōŋ 80 Ž R ĘĜəÂöä ÆøzŸõ ŵŋ ȟ 1.25ş R ÿzÈèÅkzĜöä Æăźz ŵŋ ȟ 3.5 āäØ *:Procedure öäÄDZq*
Ż .ZÈÀǹ ÀþÜ ɉzŸä ĞäÅèø ʔŎĞ ʔøQģ öÅţä Ž R ĘĜəÂöä ÆøzŸõ ŵŋ ǻøÅä ȜĜÎŋ òzŸŢ ŌÀÀĦQöä öÅQÜ ȣÅȒ
ŵŋ ȜĜÎŋ òzŸŢ ŵŋ ĞŸÈŸę ģǻÀä ȣÅȒ ÛɉÅäşØöä ʔøQģ ǯÂŧłş R ÿzăźzÔöä ÆÊõşøÆĿ ŵŋ ȟ 12 ȣÅȒ
ŌəÅÊöä ɉÅĞłş ĞȝÅè 24 øäÀŌQèŸö õÀQ ÜŌŋ 100 ǇDzģ ʔŸȝ òzÔĦŸö öÅţä ŵŋ ȣÅõ øäÆŌŋş R ĘĜəÂöä ÆøzŸõ
.ŽÅÔöä

.(147 ĞĦÀÔöä Û1963 ÛSRIP) $KBrO_3$ ¦**Potassium bromate R** ÿzÈèÅkzĜöä ğÅŋşÀä

ĞäÀę ɃzȜ R ÿzÈèÅkzĜöä ğÅŋşÀä òzŸŢ ¦**TS** (ò ȟ **50**) **Potassium bromate** ÿzÈèÅkzĜöä ğÅŋşÀä òzŸŢ
.ÀQö 1 Ōõ Ž $KBrO_3$ ŵŋ ȟ 50

öÅţä Ž ĞäØŀ ÛR ÿzÈèÅkzĜöä ğÅŋşÀä ¦**VS** (ò òzŋ **0. 0167**) **Potassium bromate** ÿzÈèÅkzĜöä ğÅŋşÀä òzŸŢ
.Ōŋ 1000 Ž $KBrO_3$ ŵŋ ȟ 2.784 ɃzĦÈö

ĞäÀę ɃzȜ R ÿzÈèÅkzĜöä ÆŋşÀä òzŸŢ ¦**TS** (ò ȟ **0.119**) **Potassium bromide** ÿzÈèÅkzĜöä ÆŋşÀä òzŸŢ
.ÀQö 1 Ōõ Ž KBr ŵŋ ȟ0.1190

.(152 ĞĦÀÔöä Û1963 ÛSRIP) K_2CrO_4 ¦**Potassium chromate R** ÿzÈèÅkzĜöä ğÅŋşÀõ

ĞäÀę ɃzȜ R ÿzÈèÅkzĜöä ğÅŋşÀõ òzŸŢ ¦**TS** (ò ȟ **100**) **Potassium chromate** ÿzÈèÅkzĜöä ğÅŋşÀõ òzŸŢ
.(ÅĜÀŌĞ ò/òzŋ 0.5) ÀQö 1 Ōõ Ž ȟ K_2CrO_4 ŵŋ ȟ 97

.(153 ĞĦÀÔöä Û1963 ÛSRIP) KCN ¦**Potassium cyanide R** ÿzÈèÅkzĜöä ÆøÅÈè

ȟ 100 ĞäÀę ɃzȜ R ÿzÈèÅkzĜöä ÆøÅÈè òzŸŢ ¦**TS** (ò ȟ **100**) **Potassium cyanide** ÿzÈèÅkzĜöä ÆøÅÈè òzŸŢ
.ÀQö 1 Ōõ Ž KCN ŵŋ

ŵŋ ȟ 50 ĞäÀę ɃzȜ R ÿzÈèÅkzĜöä ÆøÅÈè òzŸŢ ¦**TS** (ò ȟ **50**) **Potassium cyanide** ÿzÈèÅkzĜöä ÆøÅÈè òzŸŢ

.ÀǬ 1 Ȭõ Ž KCN

Ƀζʒ R ӯζȅĚÀǩζǤǒ ğÀŋşÀõ ƟəÀǬ ȯζŸʈ ؛**TS** (ȯ ȟ **100**) **Potassium dichromate** ӯζȅĚÀǩζǤǒ ğÀŋşÀõ ƟəÀǬ
.(ǨǤÀǬ ȯ/ȯζŋ 0.4) ÀǬ 1 Ȭõ Ž $K_2Cr_2O_7$ ȡŋ ȟ 98 ǦǟÀę

؛**TS** (ȯ ȟ **50**) **Potassium ferricyanide** ӯζȅĚÀǩζǤǒ ǼĿǬĿȅ ɃƘζ ȯζŸʈ

ğǟǿζŸǤǒ ā ǟǾǩş ǒÀţ ȡŋ ȬĿŸȬ R ɃǿζŸǤǒ ӯζȅĚÀǩζǤǒ ǼĿǬĿȅ ɃƘζ ȡŋ ȟ 5 ǦǟÀę ȬÊȢ *:Procedure ǒǟÀǄǪ*
. Ȭŋ 100 ȴǄǵ ʔŸʒ ȯζÔǶŸ ǒÀţ ȡŋ ȣÀõ ǿǟǼȬŋ Ž ǑζÊȢţ

.ǨǄǟÀü TS (ȯ/ȟ 50) ӯζȅĚÀǩζǤǒ ǼĿǬĿȅ ɃƘζ ȯζŸʈ ÀȒʒ ȷ Ǽʑ *:Note ǦȚǵŸŋ*

.(156 ǦǶÀÔǒ Û1963 ÛSRIP) $K_4Fe(CN)_6,3H_2O$ ؛**Potassium ferrocyanide R** ӯζȅĚÀǩζǤǒ ǼĿǬĿȅşƘζ

Ƀζʒ R ӯζȅĚÀǩζǤǒ ǼĿǬĿȅşƘζ ȯζŸʈ ؛**TS** (ȯ ȟ **45**) **Potassium ferrocyandie** ӯζȅĚÀǩζǤǒ ǼĿǬĿȅşƘζ ȯζŸʈ
.ÀǬ 1 Ȭõ Ž $K_4Fe(CN)_6$ ȡŋ ȟ 50 ǦǟÀę

؛**Potassium hydroxide /ethanol TS2** ȯζǬÀʒǕ ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ

(ȯ/ȟ 710~) ȯζǬÀʒǪ ȡŋ ȣÀõ ǿǟǼȬŋ Ž R ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȡŋ ȟ 112 ā ǟǾǍ *:Procedure ǒǟÀǄǪ*
.(ǨǤÀǬ ȯ/ȯζŋ 2) Ȭŋ 1000 ȴǄǵ ʔŸʒ ȯζÔǶŸ TS

؛**Potassium hydroxide/ methanol TS** ȯζǬÀʒĿŋ ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ

ʔŸʒ ȯζÔǶŸ R ȯζǬÀʒĿţ ȡŋ ȣÀõ ǿǟǼȬŋ Ž R ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȡŋ ȟ 30 ā ǟǾȴ *:Procedure ǒǟÀǄǪ*
.Ȭŋ 1000 ȴǄǵ

ā ǟǾŋ ÛR ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ؛**VS** (ȯ ȯζŋ **0.01**) **Potassium hydroxide** ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ
.Ȭŋ 1000 Ž KOH ȡŋ ȟ 0.5610 ɃζǶĿ ǒÀţ Ž

ǦȬÀÛǒ ţÀǦǨǟ ȯζŸǶŧŸ ĘĿęǼǒ ÀĿõÀǬǒ ȡŋ ĘȬǶǬǒ ʔÀƶ *:Method of standardization ȄĿĿǬǒ ǦȬÀü*
.219 ǦǶÀÔǒ Û1 ǼŸǑǒ ÛVS (ȯ/ȯζŋ 1) ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ ȷǟζÀʒ ǨƠ Ǧζζòζţ

؛**VS** (ȯ ȯζŋ **1**) **Potassium hydroxide/ethanol** ȯζǬÀʒǕ ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ

.Ȭŋ 1000 Ž KOH ȡŋ ȟ 56.10 ɃζǶĿ TS (ȯ/ȟ 710~) ȯζǬÀʒǪ Ž ā ǟǾŋ ÛR ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ

ǦȬÀÛǒ ţÀǦǨǟ ȯζŸǶŧŸ ĘĿęǼǒ ÀĿõÀǬǒ ȡŋ ĘȬǶǬǒ ʔÀƶ *:Method of standardization ȄĿĿǬǒ ǦȬÀü*
.219 ǦǶÀÔǒ Û1 ǼŸǑǒ ÛVS (ȯ/ȯζŋ 0.5) ȯζǬÀʒǕ/ӯζȅĚÀǩζǤǒ ǼĿÊõşǿǼȽ ȯζŸʈ ȷǟζÀʒ ǨƠ Ǧζζòζţ

.(160 ǦǶÀÔǒ Û1963 ÛSRIP) KIO_3 ؛**Potassium iodate R** ӯζȅĚÀǩζǤǒ ğǟǻζǍ

ɃζǶĿ ǒÀţ Ž ǦǟǾŋ ÛR ӯζȅĚÀǩζǤǒ ğǟǻζǍ ؛**VS** (ȯ ȯζŋ **0.05**) **Potassium iodate** ӯζȅĚÀǩζǤǒ ğǟǻζǍ ȯζŸʈ

.Ōŋ 1000 Ž KIO_3 ȸŋ ȟ 10.70

ȯ/ȯζŋ 0.05 ÂĿõÀǪǿ ȯζŸǂ ĘĿęÆöä ÂĿõÀǪöä ȸŋ ĘŌԋǪöä ʔÀƶ :*Method of standardization* *ÈĿĿŌǪöä ǓŌʌÄü*
200 øǿ ƵÀÁł ÛǦĿDZÀDZà gåäÆÊǿ gåşÂŋ ǦŸDZζǵ Ž ӯζĿèÀǩζǤöä ğäåζʌ ȯζŸƮ ȸŋ Ōŋ 10.0 ȝȑζʌ :ǦĿöÀǪöä ǓŌʌÀÛöÀǿ
ōÀǪʌ .TS (ȯ/ȟ 100~) ŌʌøζÀŸÊöä Ȑƥ ȸŋ Ōŋ 25ş ÛR ӯζĿèÀǩζǤöä ÆʌåζʌȸŋȟȝȢÀȒʌ ÛöÀţǟ ȸŋ Ōŋ
3 ȢÀȒł ÛVS (ȯ/ȯζŋ 0.1) ӯζʌåζÔöä ğÀÀŸèζĿǭ ȯζŸԋŋ øÀԋǪţǟ åζĿöä ÀÀÀĦʌş ĘǝÀęå 10 gÆŋ øäÀŌǪèŸö ȯζŸǂä
ȸŋ ÀƮÊÀφ ğÀĿŧÔöä ʔŸȝ ȸĦĽţǟ ÆŁÀÎöä ÆÊШ ǴԋÔł .ǦʌÀƮʌöä ǦÛŌφ āÀǪŌǩ ÀŋÆʌȝ TS ÀÎʌöä ȯζŸƮ ȸŋ Ōŋ
.ÀƮÊÀφ Ƶȉäζ Ôöä

Ƀζԋ Ŀö ŏÀţǟ Ž ǦääØŋ ÛR ӯζĿèÀǩζǤöä ğäåζʌ ¦**VS** (ȯ ȯζŋ **0.01**) **Potassium iodate** ӯζĿèÀǩζǤöä ğäåζʌ ȯζŸƮ
.Ōŋ 1000 Ž KIO3 ȸŋ ȟ 2.140

ǓŌʌÀÛöä ţÀǦǩÀǿ ȯζŸԋŧŸö ĘĿęÆöä ÂĿõÀǪöä ȸŋ ĘŌԋǪöä ʔÀƶ :*Method of standardization* *ÈĿĿŌǪöä ǓŌʌÄü*
.VS (ȯ/ȯζŋ 0.05) ӯζĿèÀǩζǤöä ğäåζʌ ȯζŸƮ ȷäζȝ ǨƠ Ǧζζȍζţǟ

ȸŋ ȟ 400 ǦääÀę Ƀζȝ R ӯζĿèÀǩζǤöä ÆʌåζʌȯζŸƮ ¦**TS** (ȯ ȟ **400**) **Potassium iodide** ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ
.ÀǪö 1 Ōõ Ž KI

ȸŋ ȟ 300 ǦääÀę Ƀζȝ R ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ ¦**TS** (ȯ ȟ **300**) **Potassium iodide** ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ
.ÀǪö 1 Ōõ Ž KI

KI ȸŋ ȟ 60 ǦääÀę Ƀζȝ R ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ ¦**TS** (ȯ ȟ **60**) **Potassium iodide** ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ
.ÀǪö 1 Ōõ Ž

¦**Potassium iodide /starch TS1** ÀÎφ ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ

ȯζŸƮ ȸŋ Ōŋ 5 ÀƮĿöÜ ȢÀȒʌş ŏÀţǟ ȸŋ Ōŋ 95 Ž R ӯζĿèÀǩζǤöä Æʌåζʌ ȸŋ ȟ 10 āäØʌ :*Procedure* *ŏäÄDZǭǟ*
.TS ÀÎʌöä

.ÀDZàÀü TS1 ÀÎφ/ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ ÀȒȝ ȷÜ Æƶ :*Note* *ǴƮǵŸŋ*

¦**Potassium iodobismuthate TS1** ӯζĿèÀǩζǤöä ğÀǭζŋÂǿşåζʌ ȯζŸƮ

ɄÊõÀ ȸŋ ȟ 8.5 ȢÀȒłş ŏÀţǟ ȸŋ Ōŋ 400 Ž R ŌʌÀüÀÛöä Ȑƥ ȸŋ ȟ 100 āäØʌ :*Procedure* *ŏäÄDZǭǟ*
ÛTS (ȯ/ȟ 400) ӯζĿèÀǩζǤöä Æʌåζʌ ȯζŸƮ ȸŋ Ōŋ 200 ȢÀȒʌ ÛǦȝÀè 1 gÆŋ ȯζŸǂä ȐƩ .R ğζŋÂǤöä ğäÀǪφ
.ǴȉÀʌş ǦȝÀè 24 gÆŋ øäÀŌǪèŸö ōÀǪł .ȝÂŧłş

[illegible] **Potassium iodobismuthate TS2**

Procedure [illegible] 100 [illegible] 500 [illegible] 50 [illegible]

[illegible] TS1.

[illegible] **Potassium iodoplatinate TS**

Procedure [illegible] 2.5 [illegible] 50 [illegible] 45 [illegible]

[illegible] 0.1 [illegible] 100 [illegible].

Storage [illegible].

[illegible] **Potassium periodate R**؛ KIO_4 (SRIP 1963 [illegible] 164).

[illegible] **Potassium periodate TS**

Procedure [illegible] 2.8 [illegible] R [illegible] 200 [illegible] 20 [illegible]

[illegible] (~1760 [illegible]) TS [illegible]

[illegible] 1000 [illegible].

[illegible] **Potassium permanganate** (**0.002** [illegible]) **VS**؛ [illegible] R [illegible]

[illegible] 0.3161 [illegible] $KMnO_4$ [illegible] 1000.

Method of standardization [illegible]

[illegible] (0.02 [illegible]) VS [illegible] 1 [illegible] 221.

Potassium sodium tartrate R [illegible] R

Sodium potassium tartrate؛ $C_4H_4KNaO_6,4H_2O$ (SRIP 1963 [illegible] 193).

[illegible] **Potassium thiocyanate R**؛ KCNS. [illegible] 99.0% [illegible] KCNS [illegible]

[illegible].

Description [illegible].

Solubility [illegible] 0.5 [illegible] 15 [illegible] R.

Alkalinity [illegible] 0.1 [illegible] R [illegible]

[illegible] TS.

Ammonia [illegible] 1.0 [illegible] 5 [illegible] (~80 [illegible]) TS [illegible]

[illegible].

Chlorides [illegible] 1.0 [illegible] 1 [illegible] R [illegible] 30 [illegible]

[illegible] 1 [illegible] 1 [illegible] TS (ò/ȟ 60~) [illegible]
[illegible] 30 [illegible]
TS (ò/ȟ 1000~) [illegible] 5 [illegible] 2 [illegible] TS (ò/ȟ 60~) [illegible]
[illegible] TS (ò/ȟ 40) [illegible] 1 [illegible]
[illegible] VS (ò/òζ 0.01) [illegible] 1

[illegible] 20 [illegible] 0.50 [illegible] *Sulfates* [illegible]
[illegible] 1.0 [illegible] (125 [illegible] 1 [illegible]) "Limit test for sulfates [illegible]

[illegible] 2 [illegible] 50 [illegible] 1.0 [illegible] *Other sulfur compounds* [illegible]
[illegible] 0.5 [illegible] VS (ò/òζ 0.05) [illegible] TS (ò/ȟ 70~) [illegible]
.(ò/òζ 0.05)

20 [illegible] °105 [illegible] *Loss on drying* [illegible]

[illegible] 5 [illegible] 50 [illegible] 0.4 [illegible] *Assay* [illegible]
[illegible] 5 VS (ò/òζ 0.1) [illegible] 50 TS (ò/ȟ 1000~) [illegible]
(ò/òζ 0.1) [illegible] TS (ò/ȟ 45) [illegible]
.KCNS [illegible] 9.718 [illegible] VS (ò/òζ 0.1) [illegible] 1 [illegible] .VS

[illegible] R [illegible] *Note* [illegible]

[illegible] **Prednisolon RS** [illegible]

[illegible] **Primaquin diphosphate RS** [illegible]

[illegible] **Procaine hydrochloride RS** [illegible]

[illegible] **Progesterone RS** [illegible]

.C_3H_8O propan-1-ol [illegible] - 1 - [illegible] n-Propanol [illegible] - *n* ؛**1-Propanol R** [illegible] **- 1**

[illegible] *Description* [illegible]

.TS (ò/ȟ 750~) [illegible] *Miscibility* [illegible]

.°98 [illegible] 95 [illegible] %95 [illegible] *Boiling range* [illegible]

[illegible] 0.803 [illegible] p_{20} *Mass density* [illegible]

[illegible] *Residue on evaporation* [illegible]

105 ° ... 0.1 ...

2 - Propanol R; 2-Propanol R - *iso*-propanol R; C_3H_8O (SRIP 1963, 167).

Propranolol hydrochloride RS

Propylene glycol R: $C_3H_8O_2$ (SRIP 1963, 168).

Pyridostigmine bromide RS

Pyrogallol R: 1,2,3-trihydroxybenzen; $C_6H_6O_3$ (SRIP 1963, 170).

Pyrogallol, alkaline, TS

Procedure: 0.5 g R 2 ml ... 12 g ... 8 ml R ...

Quinaldine red R: 2-(*p*-Dimethylaminostyryl) quinoline ethiodide; $C_{21}H_{23}IN_2$.

Description: ...

Solubility: ... TS (~750 g/l).

Melting temperature: 260 °C ...

Quinaldine red /ethanol TS

Procedure: 0.1 g R ... 100 ml ... TS (~750 g/l).

Quinaldine red /methanol TS

Procedure: 1.0 g ... 8 g ... R ... 100 ml.

Quinine R: $C_{20}H_{24}N_2O_2$.

Description: ...

Solubility: ... TS (~750 g/l) ... R ... R.

Melting temperature: 175 °C.

[illegible] TS ([illegible] 100~) [illegible] :*Identification* [illegible]

[illegible] 0.3 [illegible] 5 [illegible] 5 [illegible]

[illegible] 1 [illegible] TS1 [illegible] 0.2 [illegible] .TS ([illegible] 70~) [illegible]

.[illegible] TS ([illegible] 35~) [illegible]

.[illegible] :**Reserpine RS** [illegible]

.[illegible] :**Riboflavin RS** [illegible]

2 [illegible] .$C_7H_6O_3$:**Salicylic acid R** [illegible]

.31 [illegible]

.H_2SeO_3 [illegible] %93 [illegible] .H_2SeO_3 :**Selenious acid R** [illegible]

.[illegible] :*Description* [illegible]

.TS ([illegible] 750~) [illegible] :*Solubility* [illegible]

[illegible] 50 [illegible] 0.1 [illegible] :*Assay* [illegible]

420~) [illegible] 5 TS ([illegible] 300) [illegible] 10 [illegible]

[illegible] 50 [illegible] 10 [illegible] TS ([illegible]

[illegible] VS ([illegible] 0.1) [illegible] TS [illegible] 3

0.05) [illegible] VS ([illegible] 0.05) [illegible]

[illegible] 1 [illegible] VS([illegible] 0.1) [illegible] VS ([illegible]

.H_2SeO_3 [illegible] 3.225 [illegible] VS ([illegible] 0.1) [illegible]

:**Selenious acid/ sulfuric acid TS** [illegible]

.TS ([illegible] 1760~) [illegible] 2 [illegible] R [illegible] 10 [illegible] :*Procedure* [illegible]

.G [illegible] :**Silica gel R1** [illegible]

.[illegible] :*Description* [illegible]

[illegible] 40 - 10 [illegible] :*Composition* [illegible]

.([illegible] 130 [illegible]) [illegible]

.(254 UV) HF [illegible] :**Silica gel R2** [illegible]

.[illegible] :*Description* [illegible]

[illegible] 40 - 10 [illegible] 254 [illegible] 15 [illegible] *Composition* [illegible]

Silica gel R3 [illegible] H.

Description [illegible]

Particle size [illegible] 10-40 [illegible].

Silica gel R4 [illegible] GF (254 UV).

Description [illegible]

Composition [illegible] 40 - 10 [illegible] 130 [illegible] 254 [illegible] 15 [illegible]

Silica gel R5 [illegible] 60.

Description [illegible]

Average pore size [illegible] 6 [illegible].

Silver oxide R [illegible] Ag_2O.

Description [illegible]

Solubility [illegible] TS (~130 [illegible]) [illegible] TS (~260 [illegible]).

Substances insoluble in nitric acid [illegible] 5 [illegible] 5 [illegible] TS (~1000 [illegible]) 10 [illegible] 65 [illegible] TS (~250 [illegible]) [illegible] 1 [illegible] 105 [illegible] 0.2 [illegible].

Substances not precipitated by the hydrochloric acid [illegible] 250 [illegible] TS (~250 [illegible]) [illegible] 300 [illegible] 5 [illegible] 200 [illegible]

.ȟ/ŋŸŋ 0.5

Ōŋ 50 БǗ ZȦƸȿ Ûấ∃Ʌ ÛĞÕřȩấ 15 gǼŋ ɄəȦŋ ÿȦþ ɁŸȝ ŏȦţǟ ȸŋ Ōŋ 40 ȝŋ ȟ 2 ȸẤÊɅ *:Alkalinity ǦɅζŸÕǟ*

ȯζȺζ ȯζŸȚ ȸŋ gȀÛȩ 2 ĞÕǟȦÊǟ Ğǵȉ ȀÕǟ ȸŋ Ōŋ 25 БǗ ȣȦȒɅ .Ğǵȉ ȀÕǟ ȸŋ Ƃȿɉǟ Ōŋ 10 ɁŋȀǨ ÛǴȉ ȀɅ .ŏȦţȦǟ

ÆŸÛǬ ɍ ÜɄŸȦφȦȩ ȷζǒ ɃǗ ŏȦȂǬǹǟ ɁøǬǵ VS (ȯ/ȯζŋ 0.02) ÕɅøζŸÕȿøǼȻŢǟ ȐȶɯɅȦȞɅȿ ÛTS ȯζφȦǯɅǗ/ƙȦȫȦǯζ

.Ōŋ 0.20 ȸŋ ȀǯÕǗ

.(175 ĞɄȦÔǟ Û1963 ÛSRIP) Na :**Sodium R** ÿζɅấζÔǟ

%99.0 ȸȝ ÕÕɅ ɍ Ȧŋ ɁŸȝ ɃζǬƠ .$C_2H_3NaO_2,3H_2O$:**Sodium acetate R** ÿζɅấζÔǟ ğȦǬȻèǗ

.$C_2H_3NaO_2,3H_2O$ȸŋ

.212 ĞɄȦÔǟ Û1 ǼŸÕǟ Ž øζȊȦţǟ Õǟǽ ÕȚ БȦΣǟ ȌɅǟ Õȝ

.ȷζŸǟ ĞƹǼȝ ğǟøζŸǟ *:Description ZȍζǞ*

.TS (ȯ/ȟ 750~) ȯζφȦǯɅɋǟ Ž ȷȦǟȿØǟ ĞŸȻŸȩ ÜÕȦţǟ Ž ȻǼDZ Ğǟǟȿǽ *:Solubility ǦȻφȦǟȿØǟ*

.ȷζŸǟ ȻǼȝȿ ȺɅζȦȍ Ōŋ/ȟ 0.1 ȂȻÕȀǬǟ ȯζŸȚ ȷζȮɅ *:Clarity and colour of solution ȯζŸǂǟ ȷζǒȿ ŏȦȦȍ*

.9.2 – 7.5 ÛŌŋ/ÿǟȀȡȿȀȯŋ 50 ȂȻÕȀǬǟ ȯζŸȚ ŏȦȽȦǟ ŋŸǴɅ *:pH value ŏȦȽȦǴǟ ǦȶȻȩ*

Û1 ǼŸÕǟ) "Limit test for iron ǼɅǼΣǟ ÕDZɉ ɃǼΣǟ øȦǬȵɍǟ" БǗ ȯζŸǂǟ ÆȻDZǬÊɅ Üȟ 8 ÕȶȞǬÊɅ *:Iron ǼɅǼΣǟ*

.ȟ/ÿǟȀȡȿȀȯŋ 5.0 ȸȝ ǼɅȂɅ ɍ Ü(129 ĞɄȦÔǟ

ǨƠ ȣζȍζŋ ζȽ ȦȶÕ øȦǬȵɍǟ ȯζŸȚ ƙȒƠ ÕDZɉ ȟ 1.0 ÕȶȞǬÊɅ *:Heavy metals ĞŸȻÕǯǟ (ğǟȂŸȦǟ) ȷấȦȞţǟ*

Ü(127 ĞɄȦÔǟ Û1 ǼŸÕǟ) 1 ŏǟȀDZǗ Û"Limit test for heavy metals ĞŸȻÕǯǟ ȷấȦȞţǟ ÕDZɉ ɃǼΣǟ øȦǬȵɍǟ" ȷǟζȦȝ

.ȟ/ÿǟȀȡȿȀȯŋ 10 ȸȝ ǼɅȂɅ ɍ ÜA ĞÕɅȀÛǟ ÆÊǵ ĞŸȻÕǯǟ ȷấȦȞţǟ ɁζǬȚ ƙȞɅ

ÛБȦȣǟ ŏȦţǟ ȸŋ Ōŋ 100 Ž ȟ 1 ǟǟØɅ *:Substances reducing permanganate ğȦφȦȣȦŋƘǦŸǒ ĞǬǬȂǺȦţǟ ấǟζţǟ*

0.02) ÿζȻèȦǨζǦǟ ğȦφȦȣȦŋƘǟ ȯζŸȚ ȸŋ Ōŋ 0.05ȿ TS (ȯ/ȟ 100~) ÕɅøζȦŸÊǟ Ȑþ ȯζŸȚ ȸŋ Ōŋ 2 ȣȦȒɅ

.ĞȻŸÕ ɄŸȦφȦÕǟ ȷζŸǟ ɄȦǬƩ ɍ ÜĘəȦȩấ 5 gǼŋ ɁŸȣɅȿ ÛVS (ȯ/ȯζŋ

ȸŋ Ōŋ 5ȿ R ɄDZŸǯǟ ÕȻǬèɉǟ Ȑþ ȸŋ Ōŋ 100 Ž ÛĞȻüζǦȒŋ Ğφȿàζŋ Ûȟ 0.4 Ğǟǟȩ ǟǟØɅ *:Assay ǦÊɅȦÕţǟ*

ȀɅȦȞɅȿ ÛTS ÕȻǬèɉǟ Ȑþ/ƙɅȂøȦǟ ȯζǯζȦφ -1 ȯζŸȚ ȸŋ ğǟȀÛȩ 10 ĘəȦȩấ 5 ǼȞǟ ȣȦȒɅ .R ÕȻǬèǗ ǼɅøǼȻŒǗ

ȷǟζȦȝ ǨƠ ȣζȍζŋ ζȽ ȦȶÕ VS (ȯ/ȯζŋ 0.1) ÕɅøζŸÕƘǦǟ Ȑȶɯ ȀȒȵɉǟ ȷζŸǟ ğǟǽ ǦɅȦȽȦǟ ĞÛÕφ ɁøǬǵ

Ȑþ ȸŋ Ōŋ 1 ÕÕ (142 ĞɄȦÔǟ Û1 ǼŸÕǟ) A ĞÕɅȀÛǟ "Non-aqueous titration ɄəȦŋŸǟ ȔèζǞ Ž gȀɅȞţǟ"

.$C_2H_3NaO_2,3H_2O$ ȸŋ ŋŸŋ 13.61 üζȦȮɅ VS (ȯ/ȯζŋ 0.1) ÕɅøζŸÕƘǦǟ

ȸŋ ȟ 60 Ğǟǟȩ R ÿζɅấζÔǟ ğȦǬȻèǗ ȸŋ ȯζŸȚ Ƀζȝ :**TS (ȯ ȟ 60) Sodium acetate** ÿζɅấζÔǟ ğȦǬȻèǗ ȯζŸȚ

.ÀǬǂ 1 Ǿõ Ž $C_2H_3NaO_2$

ȸȵ ȟ 50 ǦǣǟÀę R ÿzʌázÔǟǟ ğÀǬÈèǕ ȸȵ ózŸʈ Ƀzʒ :**TS** (ó ȟ **50**) **Sodium acetate** ÿzʌázÔǟǟ ğÀǬÈèǕ ózŸʈ

.ÀǬǂ 1 Ǿõ Ž $C_2H_3NaO_2$

:**VS** (ó ózȵ **0.1**) **Sodium arsenite** ÿzʌázÔǟǟ ĶȄÀȅèøǕ ózŸʈ

ǼȄÊõşøǼȄȽ ózŸʈ ȸȵ Ōȵ 20 ȸȵ ǰʌÂȵ Ž R ŌȄÀȅèøɉǟ ǼȄÊõǕ ɄǬŸǬ ȸȵ ȟ 5 āǟØʌ :*Procedure*

70~) ŌʌøzŸõşøǼȄTǟ Ȑþ ȣÀȒʌş ǒÀʈǟǣ Ōȵ 400 ƂǕ ƵÀƩ ÛǒÀʈǟ ȸȵ Ōȵ 20ş TS (ó/ȟ 80~) ÿzʌázÔǟǟ

ƙDZşøǼȄTǟ ğÀǬzǣÀõ ȸȵ ȟ 2 āǟØʌ .R ÈȶÎǟǟ áÀǤʒ ȧøzǐ ǦǤÊÀǟÀǣ ȡɍǼǬȞȵ ózŸɨǟ ǴǤÔʌ ɁøǬǵ TS (ó/ȟ

.ǒÀʈǟǣ Ōȵ 500 ƂǕ ƵÀơş ÀȒɨǟ ózŸɨǟ Ž R ÿzʌázÔǟǟş

ǦŌʌÀÛǟǟ ʈÀǤǨÀǣ ózŸȞȶŸǂ ȨȄęǼǟǟ ÂȄõÀǬǟǟ ȸȵ ȨŌȞǬǟǟ ɁÀƶ :*Method of standardization*

.VS (ó/ózȵ 0.05) ÿzʌázÔǟǟ ĶȄÀȅèøǕ ózŸʈ ȷǟzǟʒ ĶƠ Ǧzzòzʈǟ

.ózŸɨǟ ȘÀǵ ŌDZɉ R ȨǤəÂǟǟ ȸȵ ǵÀÛę 1 ȣÀȒʌ :*Storage*

:**VS** (ó ózȵ **0.05**) **Sodium arsenite** ÿzʌázÔǟǟ ĶȄÀȅèøǕ ózŸʈ

ǼȄÊõşøǼȄȽ ózŸʈ ȸȵ Ōȵ 20 ȸȵ ǰʌÂȵ Ž R ŌȄÀȅèøɉǟ ǼȄÊõǕ ɄǬŸǬ ȸȵ ȟ 5 āǟØʌ :*Procedure*

70~) ŌʌøzŸõşøǼȄTǟ Ȑþ ȣÀȒʌş ÛǒÀʈǟǣ Ōȵ 400 ƂǕ ƵÀƩ ÛǒÀʈǟ ȸȵ Ōȵ 20ş TS (ó/ȟ 80~) ÿzʌázÔǟǟ

ƙDZşøǼȄTǟ ğÀǬzǣÀõ ȸȵ ȟ 4 āǟØʌ .R ÈȶÎǟǟ áÀǤʒ ȧøzǐ ǦǤÊÀǟÀǣ ȡɍǼǬȞȵ ózŸɨǟ ǴǤÔʌ ɁøǬǵ TS (ó/ȟ

.ǒÀʈǟǣ Ōȵ 1000 ƂǕ ƵÀƩş ÀȒɨǟ ózŸɨǟ Ž R ÿzʌázÔǟǟş

ó/ózȵ 0.05 ÂȄõÀǬǣ ózŸɨ ȨȄęǼǟǟ ÂȄõÀǬǟǟ ȸȵ ȨŌȞǬǟǟ ɁÀƶ :*Method of standardization*

ÛR ÿzʌázÔǟǟş ƙDZşøǼȄTǟ ğÀǬzǣÀõ ȸȵ ȟ 5 ȣÀȒɫ ÛǒÀʈǟ ȸȵ Ōȵ 50 øǟǼŌȵ Ōȵ 25 ƵÀƩ :ǦȄÀǬǟǟ ǦŌʌÀÛǟÀǣ

.ÀȞÎȶõ ÀÎǟǟ ózŸʈ óÀȶȞǬèÀǣ ÛVS (ó/ózȵ 0.05) ÂȄõÀǬǣ ázȄǟǟ ózŸȞȵ ÀʌÀȞʌş

.ózŸɨǟ ȘÀǵ ŌDZɉ R ȨǤəÂǟǟ ȸȵ ǵÀÛę 1 ȣÀȒʌ :*Storage*

ɄøǬǟǟ R ǦȄəÀȵŸǟǟ ÿzʌázÔǟǟ ğÀǬzǣÀõ :**Sodium carbonate, anhydrous, FeR** ÛǦȄəÀȵŸǟǟ Ûÿzʌázôǟǟ ğÀǬzǣÀõ

ŌʌøzŸõşøǼȄTǟ Ȑþ ȸȵ Ōȵ 8 ȣÀȒʌ ÛǒÀʈǟ ȸȵ Ōȵ 25 Ž ȟ 4.0 āǟØʌ :ƂÀǬǟǟ ŽÀȓɋǟ øÀǤǬȵɍǟ ƂǕ ǼȄDZǬÊǨ

Û1 ǼŸǑǟ) "Limit test for iron ǼʌǼƩǟ ŌDZɉ ɃǼƩǟ øÀǤǬȵɍǟ" Ž Àȶõ ŌȶȞǟǟ ŌȶǑʌş ÛFeTS (ó/ȟ 250~)

.ȟ/ÿǟÀȡşÀǑȵ 10 ȸʒ ǼʌÂʌ ɍ ÛFeTS ǼʌǼƩǟ ɃøÀȄȞȵ ózŸʈ ȸȵ Ōȵ 2 óÀȶȞǬèÀǣ Û(129 ǦȞÀÔǟǟ

ȸȵ ȟ200 Ƀzʒ R ÿzʌázÔǟǟ ğÀǬzǣÀõ ózŸʈ :**TS** (ó ȟ **200**) **Sodium carbonate** ÿzʌázÔǟǟ ğÀǬzǣÀõ ózŸʈ

.ÀǬǂ 1 Ǿõ Ž Na_2CO_3

ǦǟǟȀę Ƀζʒ R ӯζΛắζÔǖǟ ğȦǫζǟȀõ ȸʠ ȯζŸʈ ¦**TS** (ȯ ȟ **75**) **Sodium carbonate** ӯζΛắζÔǖǟ ğȦǫζǟȀõ ȯζŸʈ
.ȀǬǒ 1 Ȭõ Ž Na_2CO_3 ȸʠ ȟ75

R ӯζΛắζÔǖǟ ğȦǫζǟȀõ ȸʠ ȯζŸʈ Ƀζʒ ¦**TS** (ȯ ȟ **10**) **Sodium carbonate** ӯζΛắζÔǖǟ ğȦǫζǟȀõ ȯζŸʈ
.(ǋǦΛȀȬǩ ȯ/ȯζʠ 0.1) ȀǬǒ 1 Ȭõ Ž Na_2CO_3 ȸʠ ȟ10.6ǦǟǟȀę

ɃǾǖǟ ӯζΛắζÔǖǟ ǼΛǿζŸõ ¦**Sodium chloride, pyrogen-free, R** Ûʔʈ̇ŁΣǟ Ǽǭζȟ ȸʠ ƂȦʅǟ ӯζΛắζÔǖǟ ǼΛǿζŸõ
:ƂȦǬǖǟ ŽȦȓqǟ ǿȦǬǹɍǟ ƂǗ ǼǢǅǬÊΛ

ʔŁΣǟ ğǟǼǖζʠ ȬǅǰǾȦǬǹɍǟ" ȷǟζΛʒ ǨƠ ȣζȍζʠ ζȽ ȦŁõ ǿȦǬǹɍǟ ĘǦÛƚ *:Pyrogens ʔŁΣǟ ğǟǼǭζʠ*
10 Ž ŋŸʠ 9 Ƀζʒ ȯζŸʈ ÛǼǫǿɉǟ ȷȁş ȸʠ ŋŸõ 1 ȬȮǒ ÛȸȬɰ (165 ǦǶȦÔǖǟ Û1 ǼŸȬǟ) "Test for pyrogens
.R ɭǢȫʒ ǒȦʠ Ȭʠ

$C_5H_{10}NNaS_2,3H_2O$ ¦**Sodium diethyldithiocarbamate R** ӯζΛắζÔǖǟ ğȦʠȦǟȀʠζǢǬ ɄəȦǬ ȬǢʒΛǗ ɄəȦǬ
.(183 ǦǶȦÔǖǟ Û1963 ÛSRIP)

Ƀζʒ ¦**TS** (ȯ ȟ **0.8**) **Sodium diethyldithiocarbamate** ӯζΛắζÔǖǟ ğȦʠȦǟȀõζǢǬ ɄəȦǬ ȬǢʒΛǗ ɄəȦǬ ȯζŸʈ
.ȀǬǒ 1 Ȭõ Ž $C_5H_{10}NNaS_2$ ȸʠ ȟ 0.8 ǦǟǟȀę R ӯζΛắζÔǖǟ ğȦʠȦǟȀõζǢǬ ɄəȦǬ ȬǢʒΛǗ ɄəȦǬ ȸʠ ȯζŸʈ

Sodium ӯζΛắζÔǖǟ ǦǢəȦǬ ğȦȦÊǉ ¦**Sodium dihydrogen phosphate R** ƙǅşǿǼǢȾǟ ǦǢəȦǬ ӯζΛắζÔǖǟ ğȦȦÊǉ
NaH_2PO_4,H_2O Ümonobasic âȦèɉǟ ǦΛắȦǵǖ ÛSodium phosphate ӯζΛắζÔǖǟ ğȦȦÊǉ Ü biphosphate
.(178 ǦǶȦÔǖǟ Û1963 ÛSRIP)

ğȦȦÊǉ ȯζŸʈ ¦**TS** (ȯ ȟ**45**) **Sodium dihydrogen phosphate R** ƙǅşǿǼǢȾǟ ǦǢəȦǬ ӯζΛắζÔǖǟ ğȦȦÊǉ ȯζŸʈ
.ȀǬǒ 1 Ȭõ Ž NaH_2PO_4 ȸʠ ȟ 47 ǦǟǟȀę Ƀζʒ R ƙǅşǿǼǢȾǟ ǦǢəȦǬ ӯζΛắζÔǖǟ

$NaHCO_3$ Ü ӯζΛắζÔǖǟ ǦǢəȦǬ ğȦǫζǟȀõ ¦**Sodium hydrogen carbonate R** ӯζΛắζÔǖǟş ƙǅşǿǼǢȾǟ ğȦǫζǟȀõ
.(177 ǦǶȦÔǖǟ Û1963 ÛSRIP)

ğȦǫζǟȀõ ȯζŸʈ ¦**TS** (ȯ ȟ **40**) **Sodium hydrogen carbonate R** ӯζΛắζÔǖǟş ƙǅşǿǼǢȾǟ ğȦǫζǟȀõ ȯζŸʈ
.(ȯ/ȯζʠ 0.5 ǋǦΛȀȬǩ) ȀǬǒ 1 Ȭõ Ž $NaHCO_3$ ȸʠ 42 ǦǟǟȀę Ƀζʒ R ӯζΛắζÔǖǟş ƙǅşǿǼǢȾǟ

Ƀζʒ R ӯζΛắζÔǖǟ ǼǢÊõşǿǼǢȽ ȯζŸʈ ¦**TS** (ȯ ȟ **150~**) **Sodium hydroxide** ӯζΛắζÔǖǟ ǼǢÊõşǿǼǢȽ ȯζŸʈ
.ȀǬǒ 1 Ȭõ Ž NaOH ȸʠ ȟ150 ǦǟǟȀę

ǦǟǟȀę Ƀζʒ R ӯζΛắζÔǖǟ ǼǢÊõşǿǼǢȽ ȯζŸʈ ¦**TS** (ȯ ȟ **10**) **Sodium hydroxide** ӯζΛắζÔǖǟ ǼǢÊõşǿǼǢȽ ȯζŸʈ
.(ǋǦΛȀȬǩ ȯ/ȯζʠ 0.25) ȀǬǒ 1 Ȭõ Ž NaOH ȸʠ ȟ10

[illegible] Sodium hydroxide/ methanol TS:

Procedure: [illegible] 40 [illegible] R [illegible] R [illegible] 1000 [illegible].

[illegible] Sodium hydroxide (0.5 [illegible]) VS: [illegible] R [illegible] 20.00 [illegible] NaOH [illegible] 1000 [illegible].

Method of standardization: [illegible] (1 [illegible]/[illegible]) VS [illegible] 1 [illegible] 224.

[illegible] Sodium hydroxide (0.02 [illegible]) VS: [illegible] R [illegible] 0.8001 [illegible] NaOH [illegible] 1000 [illegible].

Method of standardization: [illegible] (1 [illegible]/[illegible]) VS [illegible] 1 [illegible] 224.

[illegible] Sodium hydroxide (0.001 [illegible]) VS: [illegible] R [illegible] 40.01 [illegible] NaOH [illegible] 1000 [illegible].

Method of standardization: [illegible] (1 [illegible]/[illegible]) VS [illegible] 1 [illegible] 224.

[illegible] (~40 [illegible]) TS:

Description: [illegible].

Assay: [illegible] 3 [illegible] 50 [illegible]. [illegible] 2 [illegible] R [illegible] 10 [illegible] (~300 [illegible]/[illegible]) TS [illegible] 3 [illegible] TS [illegible] (0.1 [illegible]/[illegible]) VS [illegible] 1 [illegible] (0.1 [illegible]/[illegible]) VS [illegible] 3.723 [illegible] NaOCl.

Storage: [illegible] (~40 [illegible]/[illegible]) [illegible] 25°[illegible].

[illegible] Sodium hypochlorite TS1:

Procedure: [illegible] 10 [illegible] (~40 [illegible]/[illegible]) TS [illegible] 100 [illegible] (0.50% [illegible]).

[illegible] Sodium metabisulfate R: $Na_2O_5S_2$ (SRIP [illegible] 1963 [illegible] 187).

[illegible] .$NaIO_4$ [illegible] :**Sodium metaperiodate R** [illegible]
.$NaIO_4$ [illegible] %98.0
. [illegible] :*Description* [illegible]
. [illegible] :*Solubility* [illegible]
[illegible] 3 R [illegible] 3 [illegible] 100 [illegible] 0.5 [illegible] :*Assay* [illegible]
[illegible] 1 [illegible] .VS (0.05 [illegible]) [illegible] R [illegible]
.$NaIO_4$ [illegible] 10.69 [illegible] VS (0.05 [illegible]) [illegible]

:**VS** (**0.1** [illegible]) **Sodium methoxide** [illegible]
[illegible] 2.5 [illegible] R [illegible] 150 [illegible] :*Procedure* [illegible]
[illegible] R [illegible] R [illegible]
. [illegible] 1000 [illegible]
[illegible] 0.1 [illegible] :*Method of standardization* [illegible]
[illegible] 0.10 [illegible]
[illegible] 12.21 [illegible] .(142 [illegible] 1 [illegible]) B [illegible] "Non-aqueous titration [illegible]"
.VS (0.1 [illegible]) [illegible] 1 [illegible] $C_7H_6O_6$
. [illegible] VS (0.1 [illegible]) [illegible] :*Note* [illegible]

:**Sodium molybdotungstophosphate TS** [illegible]
[illegible] 50 [illegible] 350 [illegible] :*Procedure* [illegible]
(~1440 [illegible]) [illegible] 25 [illegible] 12 [illegible] R [illegible]
. [illegible] 500 [illegible] TS

.$C_{10}H_5NaO_5S$:Sodium 1,2-naphtoquinone-4-sulfonate R [illegible] - 4 - [illegible] - 2 [illegible] 1
. [illegible] :*Description* [illegible]
.TS (~750 [illegible]) [illegible] :*Solubility* [illegible]
(5 [illegible]) :**Sodium 1,2-naphtoquinone-4-sulfonate** [illegible] **- 4 -** [illegible] **- 2** [illegible] **1** [illegible]
. [illegible] 1 [illegible] $C_{10}H_5NaO_5S$ [illegible] 5 [illegible] R [illegible] - 4 - [illegible] - 2 [illegible] 1 [illegible] :TS
[illegible] 100 [illegible] R [illegible] :**TS** (**100** [illegible]) **Sodium nitrite** [illegible]
. [illegible] 1 [illegible] $NaNO_2$

$NaNO_2$ ȹŋ ȟ 3 ǦǟǟȂę ɃɀƷ R ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ :**TS** (ȯ ȟ **3**) **Sodium nitrite** ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ
.ȂǬǿ 1 ȌȭŽ

.ǟDZǟȂü TS (ȯ/ȟ 3) ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ ȂȒƷ ȷ Ǣƶ :*Note ǦȚǵȲŋ*

$NaNO_2$ ȹŋ ȟ 1 ǦǟǟȂę ɃɀƷ R ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ :**TS** (ȯ ȟ **1**) **Sodium nitrite** ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ
.ȂǬǿ 1 ȌȭŽ

.ǟDZǟȂü TS (ȯ/ȟ 1) ӯɀȂǻɀȎǿǟ ǨȂȂǬ ȯɀȲȚ ǨȒƠ Ǣƶ :*Note ǦȚǵȲŋ*

.(190 ǦȞȂȎǿ Ȗ1963 ȖSRIP) $Na_2Fe(NO)(CN)_5,2H_2O$:**Sodium nitroprusside R** ӯɀȂǻɀȎǿǟ ǢȄȅȂȅȂǬ

ɃɀƷ R ӯɀȂǻɀȎǿǟ ǢȄȅȂȅȂǬ ȯɀȲȚ :**TS** (ȯ ȟ **45**) **Sodium nitroprusside R** ӯɀȂǻɀȎǿǟ ǢȄȅȂȅȂǬ ȯɀȲȚ
.ȂǬǿ 1 ȌȭŽ $Na_2Fe(NO)(CN)_5$ ȹŋ ȟ 45 ǦǟǟȂę

.ǟDZǟȂü TS (ȯ/ȟ 45) ӯɀȂǻɀȎǿǟ ǢȄȅȂȅȂǬ ȯɀȲȚ ǨȒƠ Ǣƶ :*Note ǦȚǵȲŋ*

ӯɀȂǻɀȎǿǟ ǧǟǿɀǟ Ʉɜȶǿ ȹŋ ȯɀȲȚ ɃɀƷ :**TS** (ȯ ȟ **10**) **Sodium tetraborate** ӯɀȂǻɀȎǿǟ ǧǟǿɀǟ Ʉɜȶǿ ȯɀȲȚ
.ȂǬǿ 1 ȌȭŽ $Na_2B_4O_7$ ȹŋ ȟ 10 ǦǟǟȂę R

ǦǟǟȂę R ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ ȹŋ ȯɀȲȚ ɃɀƷ :**TS** (ȯ ȟ **320**) **Sodium thiosulfate** ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ ȯɀȲȚ
.ȂǬǿ 1 ȌȭŽ $Na_2S_2O_3$ ȹŋ ȟ 320

ǦȞȂȎǿ Ȗ1 ǢȲȌǟ Ƃƶ ƂȂǬǿ ȚȎȂǟ ȣȂȒȽ :**VS** (ȯ ȯɀŋ **0.1**) **Sodium thiosulfate** ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ ȯɀȲȚ
.229

0.1 ȂȄȭȂǬǟ ȯɀȲǂ ĘȄęǢǿǟ ȂȄȭȂǬǿǟ ȹŋ ĘȌȞǬǿǟ ɁȂƶ :(ȌȂǢǟ ǿǟȂDZȖ) *Method of standradization ȀȄȌǬǿǟ ǦȌȂü*

ǿǟǢȌŋ ǦȄDZȂDZǟ ǥǟǟǢȅ ǧǟǟ ǦȄùȅȂƯ ǦȲDZɀǵ Ž ǦɜɀȒɀŋ ǿȂȶǟ ȹŋ Ȍŋ 40 ǦǟǟȂę Ƃƶ ȣȂȒȽ :ǦȄǿȂǬǿǟ ǦȌȂȖǿǟ ȯ/ȯɀŋ

ȹŋ Ȍŋ 3ş ȖR ӯɀȄȅȂȂǦǿǟ ǢȂǻɀȂ ȹŋ ȟ 1 ǿǟǢȌŋş ȖVS (ȯ/ȯɀŋ 0.0167) ӯɀȄȅȂȂǦǿǟ ǧȂŋşȂǟ ȯɀȲȚ Ȍŋ 10.0

ȯɀȲȞŋ ǿȂȞǬȶǟ ǻɀȄǿǟ ȂȂȞȂş ȖĘǟȂęǻ 5 ǥǢŋ ǿǟȂȌǬȅȲǿ ȯɀȲǂǟ ȭȂǬȂ .TS (ȯ/ȟ 1760~) ȌȂǿɀȂȆǿǟ Ȑƥ

ƻȲƷ ǢȽȂȉ ǨȄȞǨ ȂDZȂɫ .ǦȂȂȚȂǿǟ ǦȖȌǬ Ƃƶ ȯɀȍɀǿǟ ȌȄǦ TS ȂȊȂǿǟ ȯɀȲȚ ȹŋ Ȍŋ 3 ȣȂȒȽ ȖӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ
.ǦȂǿȅȂȑ ǧȂȞȄȞȎǨ ǦȂƶ ɁȂθş Ȥȉȁɀȯǿǟ ȹŋ ȂȚȆȂǬ ǧȂȄȶȯǿǟ

ǿȂȶǟ Ž ǦǟǿǟŋȖR ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ :**VS** (ȯ ȯɀŋ **0.02**) **Sodium thiosulfate** ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ ȯɀȲȚ
.Ȍŋ 1000 Ž $Na_2S_2O_3$ ȹŋ ȟ 3.164 ɃɀȞȄǿ

ǦȌȂȖǿǟ ȶȂǦǨȂǟ ȯɀȲȞȶȲǿ ĘȄęǢǿǟ ȂȄȭȂǬǿǟ ȹŋ ĘȌȞǬǿǟ ɁȂƶ :*Method of standardization ȀȄȌǬǿǟ ǦȌȂü*
.VS(ȯ/ȯɀŋ 0.1) ӯɀȂǻɀȎǿǟ ǧȂȂȲȅɀȄǬ ȯɀȲȚ ȷǟɀȂɜ ǨƠ Ǧɀɀȍɀȶǟ

[illegible] **Sodium tungstate R**: $Na_2O_4W,2H_2O$ (SRIP 1963 [illegible] 197).

[illegible] **Sorbitol R**: $C_6H_{14}O_6$. [illegible] 97.0% [illegible] $C_6H_{14}O_6$.

Description [illegible].

Solubility [illegible] (~750 [illegible]) TS [illegible]

[illegible] R.

Assay [illegible] 0.2 [illegible] 100 [illegible] 10.0 [illegible] 50.0 [illegible] TS [illegible]

[illegible] R [illegible] 2.5 [illegible] 15 [illegible]

[illegible] VS (0.1 [illegible]) [illegible] 5 [illegible] 3 [illegible]

[illegible] 1 [illegible] TS [illegible]

[illegible] VS (0.1 [illegible]) [illegible] 1.822 [illegible] $C_6H_{14}O_6$.

Storage [illegible].

Starch iodide TS [illegible]:

Procedure [illegible] 0.75 [illegible] R [illegible] 5 [illegible] 2 [illegible] R [illegible]

[illegible] 10 [illegible] 100 [illegible]

[illegible] 5 [illegible] R [illegible] 35 [illegible].

Storage [illegible].

[illegible] **Strychnine sulfate R**: $C_{42}H_{44}N_4O_4,H_2SO_4,5H_2O$ (SRIP 1963 [illegible] 200).

[illegible] **Sulfamethoxazole RS** [illegible].

[illegible] **Sulfamethoxypyridazine RS** [illegible].

[illegible] **Sulfamic acid R**: H_3NO_3S.

Description [illegible].

Solubility [illegible] (750 [illegible]).

[illegible] **Sulfamic acid** (**50** [illegible]) **TS**: [illegible] R [illegible] 50 [illegible]

H_3NO_3S [illegible] 1 [illegible].

Note [illegible] (50 [illegible]) TS [illegible].

èŸŴĿĬĿ **Sulfanilamide RS**: ĝĳ ǦĦĎǍǹ ǦĿŧĿõ ǦĿõşå.

Ŗþ ÊǚĿŴĿ **Sulfanilic acid R**: $C_6H_7NO_3S$ (SRIP 1963 Û ÔǚĿ 201).

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (~**700** ȟ ȯ) **TS**:

ǭǚǞƺ Procedure: ŖĿ8 Ŗþ ÊǚĿǿǾ (~1760 ȟ/ȯ) TS ǚÜ Ƃ ǚşǆ ŗÊĿ ǂ ȡ ǚţ ǚǫ
ǚǫĦǆ ǛÛ Ʒǝ *d*~1.40.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (~**635** ȟ ȯ) **TS**: ŢǚǾ Ŗþ ÊǚĿǿǾ (~1760 ȟ/ȯ) TS Û ĥĀĀĀ
ǚţĀ ƗǪǚ şǚǚǚ 635 ȟ ȡ H_2SO_4 Ž õŌ 1 ǚǬǚ *d*~1.36.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (~**570** ȟ ȯ) **TS**:

ǭǚǞƺ Proceduer: ŖĿ8 ǚÜ 3 ǵǵǵ ȡ ŢǚǾ Ŗþ ÊǚĿǿǾ (~1760 ȟ/ȯ) Ƃ 7 ǵǵǵ ȡ ǚţ
ǚǫ ǚǫĦǆ ǛÛ Ʒǝ *d*~1.36.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (~**50** ȟ ȯ) **TS**

ǭǚǞƺ Procedure: ŖĿ8 Ƃ 50 Ōŉ ȡ ŢǚǾ Ŗþ ÊǚĿǿǾ (~100 ȟ/ȯ) TS şǚǚǚ 50 Ōŉ ȡ ǚţ
ǯǯ ʓ.

ŢǚǾ Ŗþ ÊǚĿǿǾ ǚǚǚǚǚ **Sulfuric acid/ ethanol TS**:

ǭǚǞƺ Procedure: ǚǚ ǚǚǚ 10 Ōŉ ȡ ǚǚǚǚ (~750 ȟ/ȯ) TS ş 90 Ōŉ ȡ Ŗþ ÊǚĿǿǾ
(~1760 ȟ/ȯ) TS Ƃ şǚǚǚ -5° ʓ ǚǚǚ8 ǚǚǚ ŖŁΣ Ƃ ǚǚǚǚ Û ǙǚǞ ǚǚǚǚ ǚǚ ǚǚ ǚǚǚ ǯǯ
ǚǚǚ.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (**0.25** ǚǚ ȯ) **VS**: ŢǚǾ Ŗþ ÊǚĿǿǾ (~1760 ȟ/ȯ) TS Û
ĥĀĀĀ ǚţĀ ƗǪǚ 24.52 ȟ ȡ H_2SO_4 Ž 1000 Ōŉ.

ǛǚǚǞ Method of standardization: ǚǚ ǚǚǚǚ ȡ ǚǚǚǚ ǚǚǚǚ ǚǚǚǚ ţǚǚǚ ǚǚǚǚ
ǚǚǚǚ ǚǚ ǚǚǚ ŢǚǾ Ŗþ ÊǚĿǿǾ (0.5 ǚǚ/ȯ) VS Û ǚǚǚ Û1 ÔǚĿ 231.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfuric acid** (**0.1** ǚǚ ȯ) **VS**: ŢǚǾ Ŗþ ÊǚĿǿǾ (~1760 ȟ/ȯ) TS Û ĥĀĀĀ
ǚţĀ ƗǪǚ 9.808 ȟ ȡ H_2SO_4 Ž 1000 Ōŉ.

ǛǚǚǞ Method of standardization: ǚǚ ǚǚǚǚ ȡ ǚǚǚǚ ǚǚǚǚ ǚǚǚǚ ţǚǚǚ ǚǚǚǚ
ǚǚǚǚ ǚǚ ǚǚǚ ŢǚǾ Ŗþ ÊǚĿǿǾ (0.5 ǚǚ/ȯ) VS Û ǚǚǚ Û1 ÔǚĿ 231.

ŢǚǾ Ŗþ ÊǚĿǿǾ **Sulfurous acid TS** **sulfurous acid R** , (SRIP 1963 Û ÔǚĿ 204).

.(205 ǦHȦÔöä Û1963 ÛSRIP) $C_4H_6O_6$ ؛**Tartaric acid R** ÕÅÅùÅÛöä Ȑþ

ȸn ȟ 10 ǦäȦę ɃζǮ R ÕÅÅùÅÛöä Ȑþ ȯζŸŢ ؛**TS (ȯ ȟ 10) Tartaric acid** ÕÅÅùÅÛöä Ȑþ ȯζŸŢ
.ÅQö 1 Ȫõ Ž $C_4H_6O_6$

$C_4H_6O_6$ ȸn ȟ 5 ǦäȦę ɃζǮ R ÕÅÅùÅÛöä Ȑþ ȯζŸŢ ؛**TS (ȯ ȟ 5) Tartaric acid** ÕÅÅùÅÛöä Ȑþ ȯζŸŢ
.ÅQö 1 Ȫõ Ž

.ǦÉöşå ǦÉəȦȶÉõ ǦÉȞDZÅŋ ĝåȦŋ ؛**Testosterone propionate RS** ȷşƘQèζQÊÉQöä ğȦqζÉäşÅä

؛**VS (ȯ ȯζŋ 0.1) Tetrabutylammonium hydroxide** ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÉÊõşøǼÉȽ ȯζŸŢ

ÛöȦţä ţşÂøÅŋ ȯζφǮÅqä ȸn Ȫŋ 90 Ž R ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÅåζÅ ȸn ȟ 40 ǟäØÅ :*Procedure* *õäÅDZqä*
Ƙ8ò ȴDzǵ ØÉÅȴ .ǦǮȦè 1 ĝǼŋ ĝǼÎä ȐƸş ÛR ʔȪÅţä ǦȒÅöä ǼÉÊõȦş ǦŋζȞÅä ǦęζȞÊţä ĝåȦţä ȸn ȟ 20 ȣȦȒɫ
R ǦȒÅöä ǼÉÊõÜ ȸn ǦÉζȦȓÜ ȟ 2 ȣȦȒÅ ÛŸȦƶÜ ȪǮȦÅǩ ǰQÅÅ ȦŋǼÅǮ .ǼÅåζÉöä ȪDZɉ ŽȦÛöä ȪəȦÊöä ƎQƸş ǰÅÂţä ȸn
ȸn ǴãÅȟ ƎǮ ǰÅÂţä ǴìÅÅ ÛǼÅåζÉöä ȸn ÅÉöȦǹ ȪəȦÊöä ǴǤÔÅ ʔøQǵ õäÅDZqä äØȽ åȦȞɫ .ǦÉζȦȓÜ ǦȪęå 30 ȐƸş
.Ȫŋ 50 ĝÅŋ Ȫõ ÛR ȣȦƨä ȸÅÂøÅǤöä ȸn ğȦȶõ ϙŸǮä ǴãÅţäş ȪǮȦÅQöä ǒȦǮş ȪÊ8Å ÛȴǮȦÅöä ÅþζȞţä ǯȦDZÂöä
ȸn ƃȦʅä ȣȦƨä ƙDZşÅQÅöä øÅȶɫ .R ȣȦƨä ȸÅÂøÅǤöȦä Ȫŋ 1000 ƃÜ ȤȦÅɫş ǦǵȦìÅöä ƃÜ ğɼȦÊ8öä ȣȦȒǩ
.ĘəȦęå 5 ĝǼŋ ȯζŸɫä ƎǮ R ȷζäÅÒöä ǼÉÊõȦ ȢəȦÅQ

ǼÉÊõşøǼÉȽ ȯζŸȞŋ R ǼÉŋȦŋøζζ ȪÉǮÉŋ ȢəȦÅQ ȸn Ȫŋ 10 ÅÅȞɫ :*Method of standardization* *ȄÉÉÕQöä ǦÕÅÅü*
ȷζö ȪÒÎQÅ ʔøQǵ ÛÅȞÎȶõ TS ȯζφǮÉŋ/ȯζȶÉǮöä ǦęøàȄ ȯζŸŢ ȸn ğäÅÛę 3 ȯȦȶȞQèȦä ÛÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø
ʔŸǮ ȯζÔȞŸö õÅȞɫ ÛǦÉüζǦȒŋ ǦφşàζţäÛR ÕÅşÂøÅǤöä Ȑþ ȸn ȟ 0.06 ǦäȦę ÉøζζȣȦȒɫ .ÒȦȦn ȧøàÜ
Ǽƶ .ǦÉqȦQ ȪŋȦÒöä ȧøàɉä ÅȞÎţä ȷζö ȪÒÎQÅ ʔøQǵ ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÉÊõşøǼÉȽ ȯζŸȞŋ ÅÅȞÅş Ûȯζ Ÿɫä
Ž ȪȶȞQÊţä ĝÅÅȞţä ȯζŸŢ ȴDzǵ ȸn .ĝÅÅȞţä ȯŸn ɃζƨäƤȦÅţä Ž ȷζäÅÒöä ǼÉÊõȦ ȢəȦÅQ ȸn ȯζŸɫä ʔȶǮ ȷÜ
ÕÅşÂøÅǤöä Ȑþ ȸn ŋŸŋ 12.21 Ȫõ .ȯ/ȯζŋ 0.1 ȯζŸȞȶŸö ĘÉęǼöä ÂÉõÅQöä ȸn ĘÕȞQöä ʕÅƶ ǦÉqȦǮöä ĝÅÅȞţä
.VS (ȯ/ȯζŋ 0.1) ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÉÊõşøǼÉȽ ȸn Ȫŋ 1 ȕζȦÒÅ

ȯȦȶȞQèɍä ȪǦę VS (ȯ/ȯζŋ 0.1) ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÉÊõşøǼÉȽ ȯζŸŢ ÅÉȞÅ ȷÜ Ǽƶ :*Note* *ǦŢǵŸŋ*
.ĝÅìȦǤŋ

ȸǮ ȪÕÅ ɍ Ȧŋ ʔŸǮ ɃζQǮ .$C_{16}H_{36}IN$ ؛**Tetrabutyl ammonium iodide R** ÿζÉqζŋɉä ȪÉǩζä ȢǮȦäø ǼÅåζÅ
.$C_{16}H_{36}IN$ ȸn %98.0

.ȐÉäÜ ȧζȞÊŋ şÜ ȐÉäÜ şÜ ȤÉÅn ȢƸÅõ ȷζŸä ğäøζŸä :*Description* *Ȥöζöä*

.TS (ό/ȟ 750~) όɀɢǻʖɋǟ Ž āǟʂǽ :*Solubility* ǦɫɢǻʂǾǚǟ

.ȟ/ɳŸɳ 0.2 ȸɜ ǼʌÂʌ ɍ :*Sulfated ash* ǨǺŸÊʈǟ ǻǻɳǺǚǟ

ǧǟÀɊ όɀŸʈ ȸɳ Ōɳ 50 ȣǺȒʌ .ŏǺʈǟ ȸɳ Ōɳ 30 Ž ÛǦɫüɀǦȒɳ Ǧɸʂàɀɳ Ûȟ 1.2 ǦǟǟÀɕ āǟØʌ :*Assay* ǦÊʌǺŌʈǟ

ǦȒǺǚǟ ǧǟÀɊ όɀŸʈ ȸɳ ǥǻʌʌÂǚǟ ÀǺǺȞǩ .TS (ό/ȟ 130~) ŌʌÀɊǺǚǟ Ȑ þ ȸɳ Ōɳ 5ʂ VS (ό/όɀɳ 0.1) ǦȒǺǚǟ

TS (ό/ȟ 45) ŌʌǼʌǼΣǟ ÿɀɫɸɀɳǚ ǧǺǺŸè όɀŸʈ όǺʈȞɊèǺǽ ÛVS (ό/όɀɳ 0.1) ÿɀɫɸɀɳɉǟ ǧǺɸǺɫèɀɫɸ όɀŸȞɳ

.$C_{16}H_{36}IN$ ȸɳ ɳŸɳ 36.94 üɀǺÓʌ VS (ό/όɀɳ 0.1) ǦȒǺǚǟ ǧǟÀɊ όɀŸʈ ȸɳ Ōɳ 1 Ōõ .ÀȞÎʈõ

Û1,1,2,2-tetrachloroethane ɈǺǯʌǚ ʂǿɀŸõ Ʉɜǻǽǿ -2Û2Û1Û1 :**Tetrachloroethanol R** ɈǺǯʌǚ ʂǿɀŸõ Ʉɜǻǽǿ

.$C_2H_2Cl_4$

.ȣǺò ÛɈɀŸǚǟ ǷǼɜ ŌǝǺè :*Descritption* ǮòɀǚǟǮ

.R ƘǭɉǟʂTS (ό/ȟ 750~) όɀɢǻʖɋǟ Ʒɳ ǯʂÂɳ ÜǒǺʈǟ ȸɳ ǒÂǅ 400 Ʒɳ ǯʂÂȟ :*Miscibility* ǦɫǅʂÂʈǟ

.°ÿ147ʂ 142 ǥǿǟÀǵ ǦǅǿǻKǽ %95 ȸɜ ŌÕʌ ɍ Ǻɳ ÀÛŌʌ :*Boiling range* ɈǺɫŸȣǚǟ όǺƒ

.1.495 – 1.493 n_D^{20} :*Refractive index* ɃǿǺÊÓɸɋǟ ǼÊǺʈǟ

.ό/ɳŸõ 1.595 – 1.590 p_{20} :*Mass density* ǦŸɸÓǚǟ ǦɀǺǯõ

.ǦɫŏʂǻǦɫǝǺɫʈɫõ ǦɫȞǅÀɳ ǥǻǺɳ :**Tetracycline hydrochloride RS** ƘŸÓɫèǟÀɊɊǚǟ ǼʌǿɀŸõʂǿǼɫȽ

.$C_{14}H_{30}$:***n*-Tetradecane R** ɈǺÓʌǻ Ʉɜǻǽǿ - ***n***

.ȣǺòʂ ɈɀŸǚǟ ǷǼɜ ŌǝǺè :*Description* ǮòɀǚǟǮ

.TS (ό/ȟ 750~) όɀɢǻʖɋǟ Ʒɳ ǯʂÂɳ :*Miscibility* ǦɫǅʂÂʈǟ

.ό/ɳŸõ 0.76 ǦǟǟÀɕ p_{20} :*Mass density* ǦŸɸÓǚǟ ǦɀǺǯõ

.1.429 – 1.428 n_D^{20} :*Refractive index* ɃǿǺÊÓɸɋǟ ǼÊǺʈǟ

Ƀɀʒ :**TS (ό ȟ 100~) Tetarmethylammonium hydroxide** ÿɀɫɸɀɳɉǟ ŌɫǯɫɳɄɜǻǽǿ ǼɫÊõʂǿǼɫȽ όɀŸʈ

.ŏǺʈǟ Ž $(CH_3)_4$ NOH ȸɳ ό/ȟ 100 ǦǟǟÀɕ

.ǦʌɀɕÛǺɫɸɀɳɉǟ ǦȞǝǟǿ ȼǤÎǨ ÛǦȞǝǟÀǚǟ ÜǭȣǺòʂ ɈɀŸǚǟ ǷǼɜ ŌǝǺè :*Description* ǮòɀǚǟǮ

1 ǥǼɳ °ÿ105 ǥǿǟÀǵ ǦǅǿǻǨ Ž ǮǺʐʂ ɄǝǺɳ ÿǺþ ʔŸɜ Ōɳ 5 ÀǺǤʌ :*Residue of evapuration* ÀǺǤɊǚǟ ȸɳ ǦǚǺʈǯǚǟ

.(ȟ/ɳŸɳ 0.2) ɳŸɳ 1.0 ȸɜ ǼʌÂǨ ɍ ǦǚǺɑ ōÀʌ ÜǦɜǺè

ȟ 0.3 ǦǟǟÀɕ üɀǺÓǨ ÛόɀŸɇǟ ȸɳ ǦɫʈõǦɫüɀǦȒɳ ɈàɀʌǨ :*Ammonia and other amines* ɁǺɳǚ ǧǺɫɳǚʂ Ǻɫɸɀɳɉǟ

ȸɳ ǦǺɫǺǹ ǥǻǺʌà ȣǺȒǨ .ŏǺʈǟ ȸɳ Ōɳ 5 Ʒɳ Ɉàɀǚǟ ǦȡÀǺɳ ŌÓÎǚǟ ǦȒǺǤɳ Ɉàʂ ǥǿʂǿǺɕ Ž Û$(CH_3)_4$NOH ȸɳ

Ž ǮǺʐʂ ÛɄǝǺɳ ÿǺþ ʔŸɜ ȣǺǺƨǟ ʔǿǬǵ ÀǺǤʌ Û(Ōɳ 4 ǦǟǟÀɕ) VS (ό/όɀɳ 1) ŌʌǿɀŸõʂǿǼɫȾǟ Ȑ þ όɀŸʈ

ﺪﻨﻋ ŊŸţİǼ ǦĿŧȮöä Ŏǧŧł ɃǾöä Û0.8317 ȴęÀöİǼ ǰǪÀ ɃǾöä ǦöÀŧǯöä ɹàş āÀȒł .Ǧ3Àè 2 gǼŊ °ÿ105 gǿäÀǵ ǦDZǿǻ
.ǦÊÀÀÖţä ﺪﻨﻋ ǰǪÀ Ʉøǫöä ǦĿŧȮöä ﺪﻨﻋ %0.2 ± ¢ǪǦÊǫ Àţ ǦÖzäzţä ($(CH_3)_4NOH$)

ﺪﻨﻋ ǦĿŧõ ȣÀȒÀ .ŏÀţä ﺪﻨﻋ Ōŋ 15 ǦäÀę ɃzƠ ǦĿDZÀDZà gåäǼÊǼ gåşÂŋ ǦŸDZzǵ ǦĿùzǦȒŋ ɹàzÀ :*Assay ǦÊÀÀÖţä*
ȯzŸȞŋ ÀÀȞÀş TS ȯzǫǯÀÜ/ÕĿǯĿţä gÀƥ ȯzŸȚ ȣÀȒÀ .ǦĿǫÀǭ ɹàzÀş Û($(CH_3)_4NOH$) ﺪﻨﻋ ȟ 0.2 ǦäÀę ùzÀȮǩ ȯzŸǂä
9.115 ùzÀȮÀ VS (ȯ/ȯzŋ 0.1) ȭÀǿzŸȭşǿǼĿŢä Ȑƥ ﺪﻨﻋ Ōŋ 1 Ȯõ .VS (ȯ/ȯzŋ 0.1) ȭÀǿzŸȭşǿǼĿŢä Ȑƥ
.($(CH_3)_4NOH$) ﺪﻨﻋ ŊŸŋ
.ÿÀȮǵüǼ ǦȭŸȣŋ ǦÀşÀǵ Ž ɹÂƩ :*Storage ﺪﻨÀÂǺǫöä*

:**Tetramethylammonium hydroxide/ ethanol TS** ȯzǫǯÀÜ ÿzĿǫzŋɉä ÕĿǯĿŋ Ʉ3Àäǿ ǼĿÊȭşǿǼĿĿ ȯzŸȚ
ǿäǼȭŋ TS (ȯ/ȟ 100~) ÿzĿǫzŋɉä ÕĿǯĿŋ Ʉ3Àäǿ ǼĿÊȭşǿǼĿĿ ȯzŸȚ ﺪﻨﻋ Ōŋ 10 ȤÀƩ :*Procedure ŏäÄDZqä*
.Ōŋ 100 ȴDZǵ ɁŸ3 ȯzÔȞŸö TS (ȯ/ȟ 750~) ȯzǫǯÀqä ﺪﻨﻋ ȣÀõ

.ǦĿöşǻ ǦĿəÀĿŧĿõ ǦĿȞDZÀŋ gåÀŋ :**4,4´-thiodianiline RS** ƙŸĿǫÜ ɃǻzĿǭ - 4´Û4
ƙǦǩ Àŋ äæÜ .ŏäzŢä ƂÜ ȏÀȞǪöä ǼÀ3 ǋòzÔǹ ÛﺪﻨÀÂǺǪöä ǼÀ3 ƙŸĿǫÜ ɃǻzĿǭ - 4´Û4 gåÀŋ ȭȮÀǪǩ :*Note ǦŢǵŸŋ*
.ÙǹÎÀţä ȴȞÀöä 3ŋ R ȯzǫǯĿţä Ž ÀŢÀŋ ȯzŸȚ ǦƨÀȞŋ gåÀţä ɁȭÀǩ ɹÜ ﺪÒƩ ÛȤĿÀǹ ȭȮÀǩ ǫşǼǵ

.(207 ǦȞÀÔöä Û1963 ÛSRIP) CH_4N_2S :**Thiourea R** ÀÀǿzÀzĿǭ
.ÀǪö 1 Ȯõ Ž CH_4N_2S ﺪﻨﻋ ȟ 0.1 ÀÀşÀÀzĿǯöä ﺪﻨﻋ ȯzŸȚ ɃzƷ :**TS (ȯ ȟ 0.1) Thiourea** ÀÀǿzÀzĿǭ ȯzŸȚ

.$C_{10}H_{14}O$:**Thymol R** ȯzŧĿǯöä
¢ǦÎǩ ÛǦÀÀÛ3 ÛǦȞəäÀöä ÜȐĿæÜ ÛɃǿzŸǼ ȧzȞÊŋ şÜ ÛɹzŸöä ǦƩǼ3 ÛgåÀ3 gǨǦõ ǧäǿzŸǼ :*Description ȤȍzŏƐ*
.ÀǪȞÊöä ǦȞəäǿ
ǋöÂDZ 1 Ž ÛTS (ȯ/ȟ 750~) ȯzǫǯÀqä ﺪﻨﻋ ŏÂDZ 1 Ž ÛöÀţä ﺪﻨﻋ ǋöÂDZ 1000 ǦäÀę Ž āäşæ :*Solubility ǦĿǫÀİşǾöä*
.R ƘǭÀɉä ﺪﻨﻋ ǋöÂDZ 1.5 Žş ÛR ÿǿzzşǿzŸȮöä ﺪﻨﻋ
gǿäÀǵ ǦDZǿǻ Ž ǦŸəÀè ɁȭǦǩ ÛgǿzŢȮţä gåÀţä ǻƎǩ ÀŋǼÀ3 Ü°ÿ51ş 48 ƙæ :*Melting range ǿÀŢȮǫɍä ȯÀƒ*
.ǼĿȞǼ Ǽǵ ƂÜ ǦȒÀǺÀŋ
Ž ǨæÀǯöä ɹàzöä ɁøǪǵ ȤÀƶş ɄəÀŋ ÿÀƥ ɁŸ3 ȟ 2 ÀÀÀÛł :*Residue on volatilization ÀÀÀÛǪöä ﺪﻨﻋ ǦöÀŧǯöä*
.ȟ/ŊŸŋ 0.5 ﺪ3 ǼÀÀǩ ɍ ǦöÀǭ ȭÀǪÀ Ü°ÿ105 gǿäÀǵ ǦDZǿǻ
.ŏzȒöä ﺪﻨﻋ ǦĿŧȚ ÛÿÀȮǵüǼ ǦȭŸȣŋ ǧÀşÀǵ Ž ɹÂƩ :*Storage ﺪﻨÀÂǺǫöä*

:**Thymol TS1** ȯzŧĿǯöä ȯzŸȚ
ȯzÔȞŸö R ɹzæÀȮöä ǼÀǿzŸȭ Ʉ3Àäǿ ﺪﻨﻋ ȣÀõ ǿäǼȭŋ Ž R ȯzŧĿǯöä ﺪﻨﻋ ȟ 0.225 āäǾÀ :*Procedure ŏäÄDZqä*

[illegible] 100 [illegible].

Thymol TS2 [illegible]:

Procedure [illegible]: [illegible] 10 [illegible] TS1 [illegible] 100 [illegible] R.

Thymol TS3 [illegible]:

Procedure [illegible]: [illegible] 10 [illegible] TS1 [illegible] 150 [illegible] R.

Thymol blue R [illegible]: [illegible] $C_{27}H_{30}O_5S$ (SRIP [illegible] 1963 [illegible] 207).

Thymol blue/ dimethylformamide TS [illegible]:

Procedure [illegible]: [illegible] 0.3 [illegible] R [illegible] R [illegible] 100 [illegible].

Thymol blue/ ethanol TS [illegible]:

Procedure [illegible]: [illegible] 0.1 [illegible] R [illegible] (~750 [illegible]) TS [illegible] 100 [illegible].

Thymol blue/ methanol TS [illegible]:

Procedure [illegible]: [illegible] 0.3 [illegible] R [illegible] R [illegible] 100 [illegible].

Thymol phtalein /dimethylformamide TS [illegible]:

Procedure [illegible]: [illegible] 0.1 [illegible] R [illegible] R [illegible] 100 [illegible].

Titanium dioxide R [illegible] TiO_2

Procedure [illegible]: [illegible].

Solubility [illegible]: [illegible] (~1760 [illegible]) TS.

Titanium dioxide/ sulfuric acid TS [illegible]:

Procedure [illegible]: [illegible] 0.1 [illegible] R [illegible] 100 [illegible] (~1760 [illegible]) TS. [illegible].

[illegible] *Storage:* [illegible]

[illegible] **Tolbutamide RS** [illegible]

[illegible] - 4 **4-Toluenesulfonamide R**: $C_7H_9NO_2S$.

[illegible] *Melting range:* 135 – 137 °.

[illegible] - 4 **4-Toluenesulfonic acid R**: $C_7H_8O_3S,H_2O$. [illegible] 98.0% [illegible] $C_7H_8O_3S$.

[illegible] *Description:* [illegible]

[illegible] *Solubility:* [illegible] (~750 [illegible]) TS [illegible] R.

[illegible] *Melting range:* 100 – 105 °.

[illegible] *Sulfated ash:* [illegible] 1.0 [illegible].

[illegible] *Assay:* [illegible] 0.8 [illegible] 50 [illegible] (0.1 [illegible]) VS [illegible] TS [illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 19.02 [illegible] $C_7H_8O_3S,H_2O$.

[illegible] - 4 **4-Toluenesulfonic acid/ ethanol TS**:

[illegible] *Procedure:* [illegible] 20 [illegible] - 4 [illegible] R [illegible] (~750 [illegible]) TS [illegible] 100 [illegible].

[illegible] **Tosylchloramide sodium R**: $C_7H_7ClNNaO_2S,3H_2O$. [illegible] 98.0% [illegible] $C_7H_7ClNNaO_2S,3H_2O$.

[illegible] *Description:* [illegible]

[illegible] *Solubility:* [illegible] 7 [illegible] 2 [illegible] (~750 [illegible]) TS [illegible] R [illegible] R.

[illegible] *Sodium chloride:* [illegible] 1.0 [illegible] 15 [illegible] R [illegible] 15 [illegible].

[illegible] *Assay:* [illegible] 0.4 [illegible] 50 [illegible] 10 [illegible] (80 [illegible]) TS [illegible] 5 [illegible] (~100 [illegible]) TS. [illegible] 10 [illegible] (0.1 [illegible]) VS. [illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 14.08 [illegible] $C_7H_7ClNNaO_2S,3H_2O$.

Note: R.

Tosylchloramide sodium TS (15):
$C_7H_7ClNNaO_2S$ 16 R 1.

Trichloroacetic acid R: $C_2HCl_3O_2$ (SRIP 1963 209).

Trichloroethylene R: C_2HCl_3.

Description:

Miscibility: R R R.

Trichlorotrifluoroethane R: 1,1,2 - 2,2,1 -
1,1,2-Trichloro-1,2,2-triflouroethane. $C_2Cl_3F_3$.

Description:

Miscibility: R R.

Trichlorotrifluoroethane TS:

Procedure: 0.05 R 1.0
R.

Triketohydrindene hydrate R: Ninhydrin, $C_9H_4O_3,H_2O$ (SRIP 1963 210).

Triketohydrindene/cadmium TS:

Procedure: 0.050 R 5 1 R 50 20 R 10.

Note:

Trimethadione RS:

Trimethoprim RS:

Trimethylpryridine R: $C_8H_{11}N$. 2,4,6-
Trimethylpyridine, Collidine.

[illegible] :*Description* [illegible]

(750~ [illegible]) [illegible] :*Miscibility* [illegible]

.R [illegible] TS

.0.914 d_4^{20} :*Relative density* [illegible]

.1.498 n_D^{20} :*Refractive index* [illegible]

[illegible] R [illegible] :TS ([illegible] 50) **Trimethylpyridine** [illegible]

.[illegible] 1 [illegible] $C_8H_{11}N$ [illegible] 50

.(211 [illegible] 1963 SRIP) $C_6H_3N_3O_7$:**Trinitrophenol R** [illegible]

[illegible] 7 [illegible] R [illegible] :TS ([illegible] 7) **Trinitrophenol** [illegible]

.[illegible] 1 [illegible] $C_6H_3N_3O_7$

:**Trinitropenol, alkaline, TS** [illegible]

[illegible] 10 [illegible] 10 [illegible] R [illegible] 20 [illegible] :*Procedure* [illegible]

.[illegible] 100 [illegible] 50 [illegible] R [illegible]

.[illegible] 48 [illegible] TS [illegible] :*Note* [illegible]

.(212 [illegible] 1963 SRIP) $C_9H_{11}NO_3$:**Tyrosin R** [illegible]

.(214 [illegible] 1963 SRIP) CH_4N_2O :**Urea R** [illegible]

.(214 [illegible] 1963 SRIP) $C_8H_8O_3$:**Vanillin R** [illegible]

.[illegible] 1 [illegible] $C_8H_8O_3$ [illegible] 10 [illegible] R [illegible] :TS ([illegible] 10) **Vanillin** [illegible]

[illegible] :**Water, ammonia-free R** [illegible]

.[illegible] TS [illegible] 2 [illegible] 50

Water, carbon-dioxide-free and ammonia-free [illegible]

[illegible] R [illegible] :**R**

.233 [illegible] 1 [illegible] R [illegible]

:[illegible] :**Water, sterile R** [illegible]

[illegible] :*Pyrogens* [illegible]

[illegible] 10 [illegible] 1 [illegible] (165 [illegible] 1 [illegible]) "Test for pyrogens

R isotonic

(215 SRIP 1963) C_8H_{10} **Xylene R**

(217 SRIP 1963) $ZnCl_2$ **Zinc chloride R**

TS (Zn 20) Zinc standard

Procedure: 4.398 R 1 (300~ TS)

100 1 1000 TS

$ZnSO_4,7H_2O$ **Zinc sulfate R** %99 %105.0

$ZnSO_4,7H_2O$.

Description:

Solubility: (750~ TS).

Clarity and colour of solution: 0.05

Chlorides: 0.7 2 (130~ TS) 30

"Limit test for chlorides"

(124 1) 0.35

Iron: 0.4 "Limit test for Iron"

(129 1) 0.10

pH value: 0.05 4.4 - 5.6.

Assay: 0.2 5 R (60~ TS)

"Complexometric titrations" (1

(138) 1 (0.05) VS 14.38 $ZnSO_4,3H_2O$.

Storage: 35

Zirconyl nitrate R %43.5 %45.5 ZrO_2

Description: R.

Solubility:

Assay: 0.1 5 R (1760~ TS)

50 5 (330~ TS)

ÕǈǿǫÀŸÊöä Ȁ þ ȯǫŸʈ ȸ Ōɳ 40 ȣÀŘǈ .TS (ȯ/ȟ 100) ȳǫŀǫɳɉä ǴŀəÀǭ ƙDZşǿǼĿ ğÀÊǫ ȸ Ōɳ 350ş

200 ȸʒ ǼǈÂǈ ɍ Àɳ ŌÊȣǈş Ǵȉ ÀǈǇ.Ǥʒè 2 ȝǼɳ °ȳ 50 – 40 ȝǿäÀǵ ǴDZǿǻ Ž ǰǈÂʈä ȘÀƷş TS (ȯ/ȟ 1760~)

ŌʒÀǬöä ŏÀÛʒÜ ʔŸʒ ȝǿǻÀę ğɍÀÊȣöä ǻǫǶǩ ɍ ʔøǬǵ TS (ȯ/ȟ 50) ÂŀÕÀǬǣ ǻǿÀǤöä ȳǫŀǫɳɉä ğäÀǬ ȯǫŸʈ ȸ Ōɳ

ǼŸŎä) "General identification tests ǦɳÀǶöä ȣäÀǶǬèɍä ğäǿÀǤǬǹä" ȷäǫǈʒ ǨƠ ȣǫȍǫʈä ğÀÊǫǫǭǿşÜ ŌDZɉ A

. ZrO_2 ȸ ȟ 0.4647 ǜǫÀǑǈ ǤöÀȶǮöä ȸ ȟ 1 Ōõ .ǨǣÀǮöä ȷàǫöä ʔøǬǵ ŌǶÎǈş ǫÀȥ .(119 ǦĦÀÔöä Û1

Zirconyl nitrate TS ŌŀǫõÀǈÂöä ğäÀǬ ȯǫŸʈ:

ÕǈǿǫŸõşǿǼŀTä Ȁ þ ȸ Ōɳ 60 ȸ ǰǈÂɳ Ž R ŌŀǫõÀǈÂöä ğäÀǬ ȸ ȟ 0.1 ǟäǾǈ :*Procedure ǒäÄDZǿ*

.ǒÀʈä ȸ Ōɳ 40ş TS (ȯ/ȟ 470~)